Dossier zur Nutzenbewertung gemäß § 35a SGB V

Dostarlimab (JEMPERLI)

GlaxoSmithKline GmbH & Co. KG

Anhang 4-G

Therapie des primär fortgeschrittenen oder rezidivierenden Endometriumkarzinoms, wenn eine systemische Therapie infrage kommt

Analysen für das Nutzendossier

Stand: 11.02.2025

Inhaltsverzeichnis

Studie 213361 (RUBY)

*Die in den Tabellen 3.3002, 3.3102, 3.3202, 3.3802, 3.3902 und 3.4002 dargestellten Subgruppenanalysen beziehen sich auf „Schwere unerwünschte Ereignisse (CTCAE-Grad ≥ 3)“.

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	178
	Return Rate[a]	96.9%	96.7%
	Return Rate[b]	96.9%	96.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	180	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.8%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	170
	Number of completed questionnaires	174	168
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.6%	91.3%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	155
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	84.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	155	156
	Number of completed questionnaires	155	152
	Return Rate[a]	100%	97.4%
	Return Rate[b]	80.7%	82.6%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.7%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	92	79
	Number of completed questionnaires	92	78
	Return Rate[a]	100%	98.7%
	Return Rate[b]	47.9%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	75	63
	Return Rate[a]	96.2%	98.4%
	Return Rate[b]	39.1%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Scale/Item: EORTC Global QOL Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	45
	Number of completed questionnaires	59	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.7%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Scale/Item: EORTC Global QOL Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Scale/Item: EORTC Global QOL Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Scale/Item: EORTC Global QOL Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Scale/Item: EORTC Global QOL Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Scale/Item: EORTC Global QOL Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	171	162
	Number of completed questionnaires	130	135
	Return Rate[a]	76.0%	83.3%
	Return Rate[b]	67.7%	73.4%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Scale/Item: EORTC Global QOL Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	185	178
	Return Rate[a]	96.4%	96.7%
	Return Rate[b]	96.4%	96.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	180	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.8%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	169
	Number of completed questionnaires	173	166
	Return Rate[a]	98.3%	98.2%
	Return Rate[b]	90.1%	90.2%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	154
	Return Rate[a]	99.4%	96.9%
	Return Rate[b]	83.9%	83.7%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	157
	Number of completed questionnaires	155	153
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	80.7%	83.2%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	112
	Return Rate[a]	98.3%	95.7%
	Return Rate[b]	61.5%	60.9%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Scale/Item: EORTC Physical Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	107	104
	Number of completed questionnaires	106	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.2%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	93	77
	Return Rate[a]	100%	97.5%
	Return Rate[b]	48.4%	41.8%
CYCLE 11 DAY 1	Number of subjects expected to complete	77	64
	Number of completed questionnaires	73	63
	Return Rate[a]	94.8%	98.4%
	Return Rate[b]	38.0%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
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Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	58	45
	Number of completed questionnaires	58	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.2%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	41
	Return Rate[a]	96.5%	95.3%
	Return Rate[b]	28.6%	22.3%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	45	37
	Return Rate[a]	95.7%	100%
	Return Rate[b]	23.4%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Scale/Item: EORTC Physical Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	96.9%
	Return Rate[b]	17.2%	16.8%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
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Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	171	162
	Number of completed questionnaires	130	133
	Return Rate[a]	76.0%	82.1%
	Return Rate[b]	67.7%	72.3%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	98
	Return Rate[a]	86.9%	82.4%
	Return Rate[b]	48.4%	53.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	48	60
	Return Rate[a]	98.0%	100%
	Return Rate[b]	25.0%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	184	178
	Return Rate[a]	95.8%	96.7%
	Return Rate[b]	95.8%	96.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	181	177
	Number of completed questionnaires	178	173
	Return Rate[a]	98.3%	97.7%
	Return Rate[b]	92.7%	94.0%
CYCLE 3 DAY 1	Number of subjects expected to complete	175	168
	Number of completed questionnaires	173	166
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.1%	90.2%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	155
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	84.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	157
	Number of completed questionnaires	156	153
	Return Rate[a]	100%	97.5%
	Return Rate[b]	81.3%	83.2%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	119	117
	Number of completed questionnaires	117	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	60.9%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	107	103
	Number of completed questionnaires	106	101
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.2%	54.9%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	93	78
	Return Rate[a]	100%	98.7%
	Return Rate[b]	48.4%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	77	64
	Number of completed questionnaires	74	63
	Return Rate[a]	96.1%	98.4%
	Return Rate[b]	38.5%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	58	45
	Number of completed questionnaires	58	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.2%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	171	162
	Number of completed questionnaires	130	135
	Return Rate[a]	76.0%	83.3%
	Return Rate[b]	67.7%	73.4%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	178
	Return Rate[a]	96.9%	96.7%
	Return Rate[b]	96.9%	96.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	179	174
	Return Rate[a]	97.8%	97.8%
	Return Rate[b]	93.2%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	170
	Number of completed questionnaires	174	168
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.6%	91.3%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	161	159
	Number of completed questionnaires	160	155
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.3%	84.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	156
	Number of completed questionnaires	156	152
	Return Rate[a]	100%	97.4%
	Return Rate[b]	81.3%	82.6%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.7%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	92	79
	Number of completed questionnaires	92	78
	Return Rate[a]	100%	98.7%
	Return Rate[b]	47.9%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	75	63
	Return Rate[a]	96.2%	98.4%
	Return Rate[b]	39.1%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	45
	Number of completed questionnaires	59	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.7%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	171	161
	Number of completed questionnaires	130	134
	Return Rate[a]	76.0%	83.2%
	Return Rate[b]	67.7%	72.8%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	178
	Return Rate[a]	96.9%	96.7%
	Return Rate[b]	96.9%	96.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	180	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.8%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	170
	Number of completed questionnaires	174	168
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.6%	91.3%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	155
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	84.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	156
	Number of completed questionnaires	156	152
	Return Rate[a]	100%	97.4%
	Return Rate[b]	81.3%	82.6%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.7%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	92	79
	Number of completed questionnaires	92	78
	Return Rate[a]	100%	98.7%
	Return Rate[b]	47.9%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	75	63
	Return Rate[a]	96.2%	98.4%
	Return Rate[b]	39.1%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	45
	Number of completed questionnaires	59	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.7%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	171	161
	Number of completed questionnaires	130	134
	Return Rate[a]	76.0%	83.2%
	Return Rate[b]	67.7%	72.8%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	177
	Return Rate[a]	96.9%	96.2%
	Return Rate[b]	96.9%	96.2%
CYCLE 2 DAY 1	Number of subjects expected to complete	182	178
	Number of completed questionnaires	179	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.2%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	170
	Number of completed questionnaires	174	168
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.6%	91.3%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	155
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	84.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	156
	Number of completed questionnaires	156	152
	Return Rate[a]	100%	97.4%
	Return Rate[b]	81.3%	82.6%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.7%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	92	79
	Number of completed questionnaires	92	78
	Return Rate[a]	100%	98.7%
	Return Rate[b]	47.9%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	75	63
	Return Rate[a]	96.2%	98.4%
	Return Rate[b]	39.1%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	65	55
	Number of completed questionnaires	65	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	33.9%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	45
	Number of completed questionnaires	59	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.7%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	171	161
	Number of completed questionnaires	130	134
	Return Rate[a]	76.0%	83.2%
	Return Rate[b]	67.7%	72.8%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	178
	Return Rate[a]	96.9%	96.7%
	Return Rate[b]	96.9%	96.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	180	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.8%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	170
	Number of completed questionnaires	174	165
	Return Rate[a]	98.9%	97.1%
	Return Rate[b]	90.6%	89.7%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	155
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	84.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	157
	Number of completed questionnaires	156	153
	Return Rate[a]	100%	97.5%
	Return Rate[b]	81.3%	83.2%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	106	101
	Return Rate[a]	98.1%	97.1%
	Return Rate[b]	55.2%	54.9%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	93	78
	Return Rate[a]	100%	98.7%
	Return Rate[b]	48.4%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	74	63
	Return Rate[a]	94.9%	98.4%
	Return Rate[b]	38.5%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	45
	Number of completed questionnaires	58	43
	Return Rate[a]	98.3%	95.6%
	Return Rate[b]	30.2%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	50	39
	Return Rate[a]	98.0%	97.5%
	Return Rate[b]	26.0%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	171	161
	Number of completed questionnaires	130	134
	Return Rate[a]	76.0%	83.2%
	Return Rate[b]	67.7%	72.8%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	98
	Return Rate[a]	86.9%	82.4%
	Return Rate[b]	48.4%	53.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	48	60
	Return Rate[a]	98.0%	100%
	Return Rate[b]	25.0%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	36	26
	Return Rate[a]	97.3%	100%
	Return Rate[b]	18.8%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	178
	Return Rate[a]	96.9%	96.7%
	Return Rate[b]	96.9%	96.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	180	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.8%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	175	168
	Number of completed questionnaires	173	166
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.1%	90.2%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	155
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	84.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	157
	Number of completed questionnaires	156	153
	Return Rate[a]	100%	97.5%
	Return Rate[b]	81.3%	83.2%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	102
	Number of completed questionnaires	107	100
	Return Rate[a]	99.1%	98.0%
	Return Rate[b]	55.7%	54.3%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	93	78
	Return Rate[a]	100%	98.7%
	Return Rate[b]	48.4%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	77	64
	Number of completed questionnaires	74	63
	Return Rate[a]	96.1%	98.4%
	Return Rate[b]	38.5%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	58	45
	Number of completed questionnaires	58	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.2%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	50	40
	Number of completed questionnaires	50	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.0%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	171	161
	Number of completed questionnaires	130	134
	Return Rate[a]	76.0%	83.2%
	Return Rate[b]	67.7%	72.8%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	117
	Number of completed questionnaires	93	98
	Return Rate[a]	86.9%	83.8%
	Return Rate[b]	48.4%	53.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	36	26
	Number of completed questionnaires	36	26
	Return Rate[a]	100%	100%
	Return Rate[b]	18.8%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	178
	Return Rate[a]	96.9%	96.7%
	Return Rate[b]	96.9%	96.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	180	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.8%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	170
	Number of completed questionnaires	174	168
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.6%	91.3%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	155
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	84.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	157
	Number of completed questionnaires	156	153
	Return Rate[a]	100%	97.5%
	Return Rate[b]	81.3%	83.2%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.7%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	93	78
	Return Rate[a]	100%	98.7%
	Return Rate[b]	48.4%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	75	63
	Return Rate[a]	96.2%	98.4%
	Return Rate[b]	39.1%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	45
	Number of completed questionnaires	59	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.7%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	171	161
	Number of completed questionnaires	130	134
	Return Rate[a]	76.0%	83.2%
	Return Rate[b]	67.7%	72.8%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	183	178
	Return Rate[a]	95.3%	96.7%
	Return Rate[b]	95.3%	96.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	180	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.8%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	168
	Number of completed questionnaires	174	166
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.6%	90.2%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	163
	Number of completed questionnaires	169	161
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	87.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	157
	Number of completed questionnaires	161	153
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	83.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	157
	Number of completed questionnaires	156	153
	Return Rate[a]	100%	97.5%
	Return Rate[b]	81.3%	83.2%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	135
	Number of completed questionnaires	141	134
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	72.8%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	107	103
	Number of completed questionnaires	106	101
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.2%	54.9%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	93	78
	Return Rate[a]	100%	98.7%
	Return Rate[b]	48.4%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	77	64
	Number of completed questionnaires	74	63
	Return Rate[a]	96.1%	98.4%
	Return Rate[b]	38.5%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	58	45
	Number of completed questionnaires	58	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.2%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	170	160
	Number of completed questionnaires	129	133
	Return Rate[a]	75.9%	83.1%
	Return Rate[b]	67.2%	72.3%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	117
	Number of completed questionnaires	93	98
	Return Rate[a]	86.9%	83.8%
	Return Rate[b]	48.4%	53.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	48	60
	Number of completed questionnaires	48	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	178
	Return Rate[a]	96.9%	96.7%
	Return Rate[b]	96.9%	96.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	181	178
	Number of completed questionnaires	178	174
	Return Rate[a]	98.3%	97.8%
	Return Rate[b]	92.7%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	175	167
	Number of completed questionnaires	173	165
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.1%	89.7%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	155
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	84.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	156
	Number of completed questionnaires	156	152
	Return Rate[a]	100%	97.4%
	Return Rate[b]	81.3%	82.6%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	107	102
	Number of completed questionnaires	106	100
	Return Rate[a]	99.1%	98.0%
	Return Rate[b]	55.2%	54.3%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	93	78
	Return Rate[a]	100%	98.7%
	Return Rate[b]	48.4%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	77	64
	Number of completed questionnaires	74	63
	Return Rate[a]	96.1%	98.4%
	Return Rate[b]	38.5%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
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Scale/Item: EORTC Insomnia Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	58	45
	Number of completed questionnaires	58	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.2%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	50	40
	Number of completed questionnaires	50	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.0%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
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Scale/Item: EORTC Insomnia Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	170	160
	Number of completed questionnaires	129	133
	Return Rate[a]	75.9%	83.1%
	Return Rate[b]	67.2%	72.3%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	117
	Number of completed questionnaires	93	98
	Return Rate[a]	86.9%	83.8%
	Return Rate[b]	48.4%	53.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	48	60
	Number of completed questionnaires	48	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	41	46
	Number of completed questionnaires	41	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.4%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	36	26
	Number of completed questionnaires	36	26
	Return Rate[a]	100%	100%
	Return Rate[b]	18.8%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	9	8
	Number of completed questionnaires	9	8
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	185	178
	Return Rate[a]	96.4%	96.7%
	Return Rate[b]	96.4%	96.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	182	178
	Number of completed questionnaires	179	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.2%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	175	168
	Number of completed questionnaires	173	166
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.1%	90.2%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	155
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	84.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	157
	Number of completed questionnaires	156	153
	Return Rate[a]	100%	97.5%
	Return Rate[b]	81.3%	83.2%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	107	101
	Number of completed questionnaires	106	99
	Return Rate[a]	99.1%	98.0%
	Return Rate[b]	55.2%	53.8%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	93	78
	Return Rate[a]	100%	98.7%
	Return Rate[b]	48.4%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	77	64
	Number of completed questionnaires	74	63
	Return Rate[a]	96.1%	98.4%
	Return Rate[b]	38.5%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	58	45
	Number of completed questionnaires	58	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.2%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	50	40
	Number of completed questionnaires	50	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.0%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	170	161
	Number of completed questionnaires	129	134
	Return Rate[a]	75.9%	83.2%
	Return Rate[b]	67.2%	72.8%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	116
	Number of completed questionnaires	93	97
	Return Rate[a]	86.9%	83.6%
	Return Rate[b]	48.4%	52.7%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	48	60
	Number of completed questionnaires	48	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	41	46
	Number of completed questionnaires	41	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.4%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	36	26
	Number of completed questionnaires	36	26
	Return Rate[a]	100%	100%
	Return Rate[b]	18.8%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	177
	Return Rate[a]	96.9%	96.2%
	Return Rate[b]	96.9%	96.2%
CYCLE 2 DAY 1	Number of subjects expected to complete	182	178
	Number of completed questionnaires	179	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.2%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	175	168
	Number of completed questionnaires	173	166
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.1%	90.2%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	155
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	84.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	157
	Number of completed questionnaires	156	153
	Return Rate[a]	100%	97.5%
	Return Rate[b]	81.3%	83.2%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	135
	Number of completed questionnaires	141	134
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	72.8%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	107	102
	Number of completed questionnaires	106	100
	Return Rate[a]	99.1%	98.0%
	Return Rate[b]	55.2%	54.3%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	78
	Number of completed questionnaires	93	77
	Return Rate[a]	100%	98.7%
	Return Rate[b]	48.4%	41.8%
CYCLE 11 DAY 1	Number of subjects expected to complete	77	64
	Number of completed questionnaires	74	63
	Return Rate[a]	96.1%	98.4%
	Return Rate[b]	38.5%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	65	55
	Number of completed questionnaires	65	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	33.9%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	58	45
	Number of completed questionnaires	58	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.2%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	50	40
	Number of completed questionnaires	50	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.0%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	171	160
	Number of completed questionnaires	130	133
	Return Rate[a]	76.0%	83.1%
	Return Rate[b]	67.7%	72.3%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	117
	Number of completed questionnaires	93	98
	Return Rate[a]	86.9%	83.8%
	Return Rate[b]	48.4%	53.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	36	26
	Number of completed questionnaires	36	26
	Return Rate[a]	100%	100%
	Return Rate[b]	18.8%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	178
	Return Rate[a]	96.9%	96.7%
	Return Rate[b]	96.9%	96.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	177
	Number of completed questionnaires	180	173
	Return Rate[a]	98.4%	97.7%
	Return Rate[b]	93.8%	94.0%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	170
	Number of completed questionnaires	174	168
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.6%	91.3%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	155
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	84.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	155	156
	Number of completed questionnaires	155	152
	Return Rate[a]	100%	97.4%
	Return Rate[b]	80.7%	82.6%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	135
	Number of completed questionnaires	141	134
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	72.8%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	107	104
	Number of completed questionnaires	106	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.2%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	91	78
	Number of completed questionnaires	91	77
	Return Rate[a]	100%	98.7%
	Return Rate[b]	47.4%	41.8%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	63
	Number of completed questionnaires	75	62
	Return Rate[a]	96.2%	98.4%
	Return Rate[b]	39.1%	33.7%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	45
	Number of completed questionnaires	59	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.7%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	32	31
	Number of completed questionnaires	32	31
	Return Rate[a]	100%	100%
	Return Rate[b]	16.7%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	24	20
	Number of completed questionnaires	24	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	12.5%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	171	161
	Number of completed questionnaires	130	134
	Return Rate[a]	76.0%	83.2%
	Return Rate[b]	67.7%	72.8%
SAFETY FOLLOW-UP	Number of subjects expected to complete	105	119
	Number of completed questionnaires	91	100
	Return Rate[a]	86.7%	84.0%
	Return Rate[b]	47.4%	54.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
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Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	185	178
	Return Rate[a]	96.4%	96.7%
	Return Rate[b]	96.4%	96.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	181	178
	Number of completed questionnaires	178	174
	Return Rate[a]	98.3%	97.8%
	Return Rate[b]	92.7%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	169
	Number of completed questionnaires	174	167
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.6%	90.8%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	158
	Number of completed questionnaires	161	154
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	83.7%
CYCLE 6 DAY 1	Number of subjects expected to complete	155	155
	Number of completed questionnaires	155	151
	Return Rate[a]	100%	97.4%
	Return Rate[b]	80.7%	82.1%
CYCLE 7 DAY 1	Number of subjects expected to complete	144	136
	Number of completed questionnaires	140	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	72.9%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	116
	Number of completed questionnaires	118	112
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	60.9%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.7%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	91	79
	Number of completed questionnaires	91	78
	Return Rate[a]	100%	98.7%
	Return Rate[b]	47.4%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	75	63
	Return Rate[a]	96.2%	98.4%
	Return Rate[b]	39.1%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	45
	Number of completed questionnaires	59	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.7%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	171	161
	Number of completed questionnaires	130	134
	Return Rate[a]	76.0%	83.2%
	Return Rate[b]	67.7%	72.8%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	25	18
	Number of completed questionnaires	25	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.0%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	17
	Number of completed questionnaires	19	17
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	9.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.1602 Summary of Return Rates in EORTC-QLQ-C30 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_1602_c30_return.sas, Output: t_2_1602_c30_return.rtf, Generated on: 30AUG2024 13:43,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	175	168
	Return Rate[a]	91.1%	91.3%
	Return Rate[b]	91.1%	91.3%
CYCLE 2 DAY 1	Number of subjects expected to complete	174	169
	Number of completed questionnaires	171	165
	Return Rate[a]	98.3%	97.6%
	Return Rate[b]	89.1%	89.7%
CYCLE 3 DAY 1	Number of subjects expected to complete	163	157
	Number of completed questionnaires	161	155
	Return Rate[a]	98.8%	98.7%
	Return Rate[b]	83.9%	84.2%
CYCLE 4 DAY 1	Number of subjects expected to complete	161	149
	Number of completed questionnaires	159	147
	Return Rate[a]	98.8%	98.7%
	Return Rate[b]	82.8%	79.9%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	150	146
	Number of completed questionnaires	149	141
	Return Rate[a]	99.3%	96.6%
	Return Rate[b]	77.6%	76.6%
CYCLE 6 DAY 1	Number of subjects expected to complete	143	138
	Number of completed questionnaires	143	135
	Return Rate[a]	100%	97.8%
	Return Rate[b]	74.5%	73.4%
CYCLE 7 DAY 1	Number of subjects expected to complete	131	120
	Number of completed questionnaires	127	119
	Return Rate[a]	96.9%	99.2%
	Return Rate[b]	66.1%	64.7%
CYCLE 8 DAY 1	Number of subjects expected to complete	111	109
	Number of completed questionnaires	109	105
	Return Rate[a]	98.2%	96.3%
	Return Rate[b]	56.8%	57.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	100	93
	Number of completed questionnaires	99	91
	Return Rate[a]	99.0%	97.8%
	Return Rate[b]	51.6%	49.5%
CYCLE 10 DAY 1	Number of subjects expected to complete	87	73
	Number of completed questionnaires	86	72
	Return Rate[a]	98.9%	98.6%
	Return Rate[b]	44.8%	39.1%
CYCLE 11 DAY 1	Number of subjects expected to complete	73	56
	Number of completed questionnaires	71	55
	Return Rate[a]	97.3%	98.2%
	Return Rate[b]	37.0%	29.9%
CYCLE 12 DAY 1	Number of subjects expected to complete	61	48
	Number of completed questionnaires	61	47
	Return Rate[a]	100%	97.9%
	Return Rate[b]	31.8%	25.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	53	38
	Number of completed questionnaires	53	36
	Return Rate[a]	100%	94.7%
	Return Rate[b]	27.6%	19.6%
CYCLE 14 DAY 1	Number of subjects expected to complete	52	40
	Number of completed questionnaires	50	39
	Return Rate[a]	96.2%	97.5%
	Return Rate[b]	26.0%	21.2%
CYCLE 15 DAY 1	Number of subjects expected to complete	47	34
	Number of completed questionnaires	47	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	24.5%	17.9%
CYCLE 16 DAY 1	Number of subjects expected to complete	44	33
	Number of completed questionnaires	43	33
	Return Rate[a]	97.7%	100%
	Return Rate[b]	22.4%	17.9%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	45	31
	Number of completed questionnaires	44	30
	Return Rate[a]	97.8%	96.8%
	Return Rate[b]	22.9%	16.3%
CYCLE 18 DAY 1	Number of subjects expected to complete	32	32
	Number of completed questionnaires	32	31
	Return Rate[a]	100%	96.9%
	Return Rate[b]	16.7%	16.8%
CYCLE 19 DAY 1	Number of subjects expected to complete	30	28
	Number of completed questionnaires	30	28
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	15.2%
CYCLE 20 DAY 1	Number of subjects expected to complete	31	29
	Number of completed questionnaires	31	29
	Return Rate[a]	100%	100%
	Return Rate[b]	16.1%	15.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 22 DAY 1	Number of subjects expected to complete	26	26
	Number of completed questionnaires	26	26
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	14.1%
CYCLE 23 DAY 1	Number of subjects expected to complete	26	26
	Number of completed questionnaires	26	26
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	14.1%
CYCLE 24 DAY 1	Number of subjects expected to complete	25	23
	Number of completed questionnaires	25	23
	Return Rate[a]	100%	100%
	Return Rate[b]	13.0%	12.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	25	23
	Number of completed questionnaires	25	22
	Return Rate[a]	100%	95.7%
	Return Rate[b]	13.0%	12.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	23	22
	Number of completed questionnaires	23	22
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	12.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	23	18
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	94.4%
	Return Rate[b]	12.0%	9.2%
CYCLE 28 DAY 1	Number of subjects expected to complete	21	15
	Number of completed questionnaires	21	15
	Return Rate[a]	100%	100%
	Return Rate[b]	10.9%	8.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	11	13
	Number of completed questionnaires	11	13
	Return Rate[a]	100%	100%
	Return Rate[b]	5.7%	7.1%
CYCLE 30 DAY 1	Number of subjects expected to complete	8	9
	Number of completed questionnaires	8	9
	Return Rate[a]	100%	100%
	Return Rate[b]	4.2%	4.9%
CYCLE 31 DAY 1	Number of subjects expected to complete	4	6
	Number of completed questionnaires	4	6
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	3.3%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	3
	Number of completed questionnaires	2	3
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	1.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	159	143
	Number of completed questionnaires	119	117
	Return Rate[a]	74.8%	81.8%
	Return Rate[b]	62.0%	63.6%
SAFETY FOLLOW-UP	Number of subjects expected to complete	98	110
	Number of completed questionnaires	84	91
	Return Rate[a]	85.7%	82.7%
	Return Rate[b]	43.8%	49.5%
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	46	52
	Number of completed questionnaires	46	52
	Return Rate[a]	100%	100%
	Return Rate[b]	24.0%	28.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	45	44
	Number of completed questionnaires	45	44
	Return Rate[a]	100%	100%
	Return Rate[b]	23.4%	23.9%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	39	39
	Number of completed questionnaires	39	39
	Return Rate[a]	100%	100%
	Return Rate[b]	20.3%	21.2%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	33	24
	Number of completed questionnaires	33	24
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	13.0%
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	27	21
	Number of completed questionnaires	27	21
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	11.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	25	15
	Number of completed questionnaires	25	15
	Return Rate[a]	100%	100%
	Return Rate[b]	13.0%	8.2%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	18	12
	Number of completed questionnaires	18	12
	Return Rate[a]	100%	100%
	Return Rate[b]	9.4%	6.5%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	9	8
	Number of completed questionnaires	9	8
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	4.3%
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	4	2
	Number of completed questionnaires	4	2
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	1.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	177	169
	Return Rate[a]	92.2%	91.8%
	Return Rate[b]	92.2%	91.8%
CYCLE 2 DAY 1	Number of subjects expected to complete	174	168
	Number of completed questionnaires	171	164
	Return Rate[a]	98.3%	97.6%
	Return Rate[b]	89.1%	89.1%
CYCLE 3 DAY 1	Number of subjects expected to complete	160	156
	Number of completed questionnaires	158	154
	Return Rate[a]	98.8%	98.7%
	Return Rate[b]	82.3%	83.7%
CYCLE 4 DAY 1	Number of subjects expected to complete	160	148
	Number of completed questionnaires	158	146
	Return Rate[a]	98.8%	98.6%
	Return Rate[b]	82.3%	79.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	148	144
	Number of completed questionnaires	147	139
	Return Rate[a]	99.3%	96.5%
	Return Rate[b]	76.6%	75.5%
CYCLE 6 DAY 1	Number of subjects expected to complete	143	137
	Number of completed questionnaires	143	134
	Return Rate[a]	100%	97.8%
	Return Rate[b]	74.5%	72.8%
CYCLE 7 DAY 1	Number of subjects expected to complete	131	119
	Number of completed questionnaires	127	118
	Return Rate[a]	96.9%	99.2%
	Return Rate[b]	66.1%	64.1%
CYCLE 8 DAY 1	Number of subjects expected to complete	111	108
	Number of completed questionnaires	109	104
	Return Rate[a]	98.2%	96.3%
	Return Rate[b]	56.8%	56.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	100	92
	Number of completed questionnaires	99	90
	Return Rate[a]	99.0%	97.8%
	Return Rate[b]	51.6%	48.9%
CYCLE 10 DAY 1	Number of subjects expected to complete	87	72
	Number of completed questionnaires	86	71
	Return Rate[a]	98.9%	98.6%
	Return Rate[b]	44.8%	38.6%
CYCLE 11 DAY 1	Number of subjects expected to complete	72	56
	Number of completed questionnaires	70	55
	Return Rate[a]	97.2%	98.2%
	Return Rate[b]	36.5%	29.9%
CYCLE 12 DAY 1	Number of subjects expected to complete	59	47
	Number of completed questionnaires	59	46
	Return Rate[a]	100%	97.9%
	Return Rate[b]	30.7%	25.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	53	38
	Number of completed questionnaires	53	36
	Return Rate[a]	100%	94.7%
	Return Rate[b]	27.6%	19.6%
CYCLE 14 DAY 1	Number of subjects expected to complete	52	40
	Number of completed questionnaires	50	39
	Return Rate[a]	96.2%	97.5%
	Return Rate[b]	26.0%	21.2%
CYCLE 15 DAY 1	Number of subjects expected to complete	46	35
	Number of completed questionnaires	46	34
	Return Rate[a]	100%	97.1%
	Return Rate[b]	24.0%	18.5%
CYCLE 16 DAY 1	Number of subjects expected to complete	43	34
	Number of completed questionnaires	42	34
	Return Rate[a]	97.7%	100%
	Return Rate[b]	21.9%	18.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	43	31
	Number of completed questionnaires	42	30
	Return Rate[a]	97.7%	96.8%
	Return Rate[b]	21.9%	16.3%
CYCLE 18 DAY 1	Number of subjects expected to complete	32	32
	Number of completed questionnaires	32	31
	Return Rate[a]	100%	96.9%
	Return Rate[b]	16.7%	16.8%
CYCLE 19 DAY 1	Number of subjects expected to complete	30	28
	Number of completed questionnaires	30	28
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	15.2%
CYCLE 20 DAY 1	Number of subjects expected to complete	31	28
	Number of completed questionnaires	31	28
	Return Rate[a]	100%	100%
	Return Rate[b]	16.1%	15.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 22 DAY 1	Number of subjects expected to complete	26	26
	Number of completed questionnaires	26	26
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	14.1%
CYCLE 23 DAY 1	Number of subjects expected to complete	26	26
	Number of completed questionnaires	26	26
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	14.1%
CYCLE 24 DAY 1	Number of subjects expected to complete	24	23
	Number of completed questionnaires	24	23
	Return Rate[a]	100%	100%
	Return Rate[b]	12.5%	12.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	25	23
	Number of completed questionnaires	25	22
	Return Rate[a]	100%	95.7%
	Return Rate[b]	13.0%	12.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	23	21
	Number of completed questionnaires	23	21
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	11.4%
CYCLE 27 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	16
	Return Rate[a]	100%	94.1%
	Return Rate[b]	12.0%	8.7%
CYCLE 28 DAY 1	Number of subjects expected to complete	19	15
	Number of completed questionnaires	19	15
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	8.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	11	13
	Number of completed questionnaires	11	13
	Return Rate[a]	100%	100%
	Return Rate[b]	5.7%	7.1%
CYCLE 30 DAY 1	Number of subjects expected to complete	8	9
	Number of completed questionnaires	8	9
	Return Rate[a]	100%	100%
	Return Rate[b]	4.2%	4.9%
CYCLE 31 DAY 1	Number of subjects expected to complete	4	6
	Number of completed questionnaires	4	6
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	3.3%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	3
	Number of completed questionnaires	2	3
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	1.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	158	140
	Number of completed questionnaires	118	114
	Return Rate[a]	74.7%	81.4%
	Return Rate[b]	61.5%	62.0%
SAFETY FOLLOW-UP	Number of subjects expected to complete	97	108
	Number of completed questionnaires	83	89
	Return Rate[a]	85.6%	82.4%
	Return Rate[b]	43.2%	48.4%
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	46	53
	Number of completed questionnaires	46	53
	Return Rate[a]	100%	100%
	Return Rate[b]	24.0%	28.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	44	43
	Number of completed questionnaires	44	43
	Return Rate[a]	100%	100%
	Return Rate[b]	22.9%	23.4%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	38	38
	Number of completed questionnaires	38	38
	Return Rate[a]	100%	100%
	Return Rate[b]	19.8%	20.7%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	33	24
	Number of completed questionnaires	33	24
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	13.0%
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	27	20
	Number of completed questionnaires	27	20
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	10.9%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	24	15
	Number of completed questionnaires	24	15
	Return Rate[a]	100%	100%
	Return Rate[b]	12.5%	8.2%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	17	12
	Number of completed questionnaires	17	12
	Return Rate[a]	100%	100%
	Return Rate[b]	8.9%	6.5%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	9	8
	Number of completed questionnaires	9	8
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	4.3%
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	4	2
	Number of completed questionnaires	4	2
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	1.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	37	46
	Return Rate[a]	19.3%	25.0%
	Return Rate[b]	19.3%	25.0%
CYCLE 2 DAY 1	Number of subjects expected to complete	35	41
	Number of completed questionnaires	32	37
	Return Rate[a]	91.4%	90.2%
	Return Rate[b]	16.7%	20.1%
CYCLE 3 DAY 1	Number of subjects expected to complete	41	40
	Number of completed questionnaires	39	38
	Return Rate[a]	95.1%	95.0%
	Return Rate[b]	20.3%	20.7%
CYCLE 4 DAY 1	Number of subjects expected to complete	40	37
	Number of completed questionnaires	38	35
	Return Rate[a]	95.0%	94.6%
	Return Rate[b]	19.8%	19.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	32	42
	Number of completed questionnaires	31	37
	Return Rate[a]	96.9%	88.1%
	Return Rate[b]	16.1%	20.1%
CYCLE 6 DAY 1	Number of subjects expected to complete	31	38
	Number of completed questionnaires	31	35
	Return Rate[a]	100%	92.1%
	Return Rate[b]	16.1%	19.0%
CYCLE 7 DAY 1	Number of subjects expected to complete	31	23
	Number of completed questionnaires	27	22
	Return Rate[a]	87.1%	95.7%
	Return Rate[b]	14.1%	12.0%
CYCLE 8 DAY 1	Number of subjects expected to complete	34	29
	Number of completed questionnaires	32	25
	Return Rate[a]	94.1%	86.2%
	Return Rate[b]	16.7%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	37	26
	Number of completed questionnaires	36	24
	Return Rate[a]	97.3%	92.3%
	Return Rate[b]	18.8%	13.0%
CYCLE 10 DAY 1	Number of subjects expected to complete	29	23
	Number of completed questionnaires	28	22
	Return Rate[a]	96.6%	95.7%
	Return Rate[b]	14.6%	12.0%
CYCLE 11 DAY 1	Number of subjects expected to complete	25	17
	Number of completed questionnaires	23	16
	Return Rate[a]	92.0%	94.1%
	Return Rate[b]	12.0%	8.7%
CYCLE 12 DAY 1	Number of subjects expected to complete	20	17
	Number of completed questionnaires	20	16
	Return Rate[a]	100%	94.1%
	Return Rate[b]	10.4%	8.7%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	14	11
	Number of completed questionnaires	14	9
	Return Rate[a]	100%	81.8%
	Return Rate[b]	7.3%	4.9%
CYCLE 14 DAY 1	Number of subjects expected to complete	16	10
	Number of completed questionnaires	14	9
	Return Rate[a]	87.5%	90.0%
	Return Rate[b]	7.3%	4.9%
CYCLE 15 DAY 1	Number of subjects expected to complete	15	9
	Number of completed questionnaires	15	8
	Return Rate[a]	100%	88.9%
	Return Rate[b]	7.8%	4.3%
CYCLE 16 DAY 1	Number of subjects expected to complete	12	8
	Number of completed questionnaires	11	8
	Return Rate[a]	91.7%	100%
	Return Rate[b]	5.7%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	16	6
	Number of completed questionnaires	15	5
	Return Rate[a]	93.8%	83.3%
	Return Rate[b]	7.8%	2.7%
CYCLE 18 DAY 1	Number of subjects expected to complete	9	7
	Number of completed questionnaires	9	6
	Return Rate[a]	100%	85.7%
	Return Rate[b]	4.7%	3.3%
CYCLE 19 DAY 1	Number of subjects expected to complete	9	8
	Number of completed questionnaires	9	8
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	4.3%
CYCLE 20 DAY 1	Number of subjects expected to complete	7	8
	Number of completed questionnaires	7	8
	Return Rate[a]	100%	100%
	Return Rate[b]	3.6%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	9	8
	Number of completed questionnaires	9	8
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	4.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	7	8
	Number of completed questionnaires	7	8
	Return Rate[a]	100%	100%
	Return Rate[b]	3.6%	4.3%
CYCLE 23 DAY 1	Number of subjects expected to complete	9	7
	Number of completed questionnaires	9	7
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	3.8%
CYCLE 24 DAY 1	Number of subjects expected to complete	8	7
	Number of completed questionnaires	8	7
	Return Rate[a]	100%	100%
	Return Rate[b]	4.2%	3.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	7
	Return Rate[a]	100%	87.5%
	Return Rate[b]	5.2%	3.8%
CYCLE 26 DAY 1	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%
CYCLE 27 DAY 1	Number of subjects expected to complete	9	9
	Number of completed questionnaires	9	8
	Return Rate[a]	100%	88.9%
	Return Rate[b]	4.7%	4.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	8	8
	Number of completed questionnaires	8	8
	Return Rate[a]	100%	100%
	Return Rate[b]	4.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	7	7
	Number of completed questionnaires	7	7
	Return Rate[a]	100%	100%
	Return Rate[b]	3.6%	3.8%
CYCLE 30 DAY 1	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
CYCLE 31 DAY 1	Number of subjects expected to complete	3	4
	Number of completed questionnaires	3	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.6%	2.2%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	1
	Number of completed questionnaires	2	1
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	67	53
	Number of completed questionnaires	27	27
	Return Rate[a]	40.3%	50.9%
	Return Rate[b]	14.1%	14.7%
SAFETY FOLLOW-UP	Number of subjects expected to complete	29	37
	Number of completed questionnaires	15	18
	Return Rate[a]	51.7%	48.6%
	Return Rate[b]	7.8%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	8	10
	Number of completed questionnaires	8	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.2%	5.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	11	4
	Number of completed questionnaires	11	4
	Return Rate[a]	100%	100%
	Return Rate[b]	5.7%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	9	4
	Number of completed questionnaires	9	4
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	8	6
	Number of completed questionnaires	8	6
	Return Rate[a]	100%	100%
	Return Rate[b]	4.2%	3.3%
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	7	3
	Number of completed questionnaires	7	3
	Return Rate[a]	100%	100%
	Return Rate[b]	3.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	3	4
	Number of completed questionnaires	3	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.6%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	2	3
	Number of completed questionnaires	2	3
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	1	1
	Number of completed questionnaires	1	1
	Return Rate[a]	100%	100%
	Return Rate[b]	0.5%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	174
	Return Rate[a]	96.9%	94.6%
	Return Rate[b]	96.9%	94.6%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	180	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.8%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	170
	Number of completed questionnaires	174	168
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.6%	91.3%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	163
	Number of completed questionnaires	169	161
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	87.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	154
	Return Rate[a]	99.4%	96.9%
	Return Rate[b]	83.9%	83.7%
CYCLE 6 DAY 1	Number of subjects expected to complete	155	157
	Number of completed questionnaires	155	154
	Return Rate[a]	100%	98.1%
	Return Rate[b]	80.7%	83.7%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.7%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	92	78
	Return Rate[a]	98.9%	98.7%
	Return Rate[b]	47.9%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	76	63
	Return Rate[a]	97.4%	98.4%
	Return Rate[b]	39.6%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	45
	Number of completed questionnaires	59	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.7%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
END OF TREATMENT	Number of subjects expected to complete	171	162
	Number of completed questionnaires	131	136
	Return Rate[a]	76.6%	84.0%
	Return Rate[b]	68.2%	73.9%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	22
	Number of completed questionnaires	29	22
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.0%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	16
	Number of completed questionnaires	19	16
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	8.7%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	2
	Number of completed questionnaires	5	2
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.1%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	185	174
	Return Rate[a]	96.4%	94.6%
	Return Rate[b]	96.4%	94.6%
CYCLE 2 DAY 1	Number of subjects expected to complete	182	178
	Number of completed questionnaires	179	173
	Return Rate[a]	98.4%	97.2%
	Return Rate[b]	93.2%	94.0%
CYCLE 3 DAY 1	Number of subjects expected to complete	175	170
	Number of completed questionnaires	173	168
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.1%	91.3%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	163
	Number of completed questionnaires	168	161
	Return Rate[a]	98.2%	98.8%
	Return Rate[b]	87.5%	87.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	154
	Return Rate[a]	99.4%	96.9%
	Return Rate[b]	83.9%	83.7%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	157
	Number of completed questionnaires	156	154
	Return Rate[a]	100%	98.1%
	Return Rate[b]	81.3%	83.7%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.7%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	92	78
	Return Rate[a]	98.9%	98.7%
	Return Rate[b]	47.9%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	76	63
	Return Rate[a]	97.4%	98.4%
	Return Rate[b]	39.6%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	45
	Number of completed questionnaires	59	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.7%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
END OF TREATMENT	Number of subjects expected to complete	171	162
	Number of completed questionnaires	131	136
	Return Rate[a]	76.6%	84.0%
	Return Rate[b]	68.2%	73.9%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	22
	Number of completed questionnaires	29	22
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.0%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	16
	Number of completed questionnaires	19	16
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	8.7%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	2
	Number of completed questionnaires	5	2
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.1%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	173
	Return Rate[a]	96.9%	94.0%
	Return Rate[b]	96.9%	94.0%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	180	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.8%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	170
	Number of completed questionnaires	174	168
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.6%	91.3%
CYCLE 4 DAY 1	Number of subjects expected to complete	170	163
	Number of completed questionnaires	168	161
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	87.5%	87.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	154
	Return Rate[a]	99.4%	96.9%
	Return Rate[b]	83.9%	83.7%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	157
	Number of completed questionnaires	156	154
	Return Rate[a]	100%	98.1%
	Return Rate[b]	81.3%	83.7%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	112
	Return Rate[a]	98.3%	95.7%
	Return Rate[b]	61.5%	60.9%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	101
	Return Rate[a]	99.1%	97.1%
	Return Rate[b]	55.7%	54.9%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	92	78
	Return Rate[a]	98.9%	98.7%
	Return Rate[b]	47.9%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	76	62
	Return Rate[a]	97.4%	96.9%
	Return Rate[b]	39.6%	33.7%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	45
	Number of completed questionnaires	59	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.7%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	27	29
	Number of completed questionnaires	27	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
END OF TREATMENT	Number of subjects expected to complete	171	162
	Number of completed questionnaires	131	134
	Return Rate[a]	76.6%	82.7%
	Return Rate[b]	68.2%	72.8%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	99
	Return Rate[a]	86.9%	83.2%
	Return Rate[b]	48.4%	53.8%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	48
	Return Rate[a]	100%	98.0%
	Return Rate[b]	25.0%	26.1%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	36	26
	Return Rate[a]	97.3%	100%
	Return Rate[b]	18.8%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	22
	Number of completed questionnaires	29	22
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.0%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	16
	Number of completed questionnaires	19	16
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	8.7%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	2
	Number of completed questionnaires	5	2
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.1%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	183	175
	Return Rate[a]	95.3%	95.1%
	Return Rate[b]	95.3%	95.1%
CYCLE 2 DAY 1	Number of subjects expected to complete	181	176
	Number of completed questionnaires	178	172
	Return Rate[a]	98.3%	97.7%
	Return Rate[b]	92.7%	93.5%
CYCLE 3 DAY 1	Number of subjects expected to complete	173	169
	Number of completed questionnaires	171	167
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	89.1%	90.8%
CYCLE 4 DAY 1	Number of subjects expected to complete	167	161
	Number of completed questionnaires	165	159
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	85.9%	86.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	160	157
	Number of completed questionnaires	159	152
	Return Rate[a]	99.4%	96.8%
	Return Rate[b]	82.8%	82.6%
CYCLE 6 DAY 1	Number of subjects expected to complete	154	155
	Number of completed questionnaires	154	152
	Return Rate[a]	100%	98.1%
	Return Rate[b]	80.2%	82.6%
CYCLE 7 DAY 1	Number of subjects expected to complete	143	133
	Number of completed questionnaires	139	132
	Return Rate[a]	97.2%	99.2%
	Return Rate[b]	72.4%	71.7%
CYCLE 8 DAY 1	Number of subjects expected to complete	119	115
	Number of completed questionnaires	117	111
	Return Rate[a]	98.3%	96.5%
	Return Rate[b]	60.9%	60.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	107	103
	Number of completed questionnaires	106	101
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.2%	54.9%
CYCLE 10 DAY 1	Number of subjects expected to complete	92	79
	Number of completed questionnaires	91	78
	Return Rate[a]	98.9%	98.7%
	Return Rate[b]	47.4%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	77	63
	Number of completed questionnaires	75	62
	Return Rate[a]	97.4%	98.4%
	Return Rate[b]	39.1%	33.7%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	54
	Number of completed questionnaires	66	53
	Return Rate[a]	100%	98.1%
	Return Rate[b]	34.4%	28.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	58	43
	Number of completed questionnaires	58	41
	Return Rate[a]	100%	95.3%
	Return Rate[b]	30.2%	22.3%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	42
	Number of completed questionnaires	55	41
	Return Rate[a]	96.5%	97.6%
	Return Rate[b]	28.6%	22.3%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	29
	Number of completed questionnaires	30	29
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	15.8%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	27
	Number of completed questionnaires	28	27
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	14.7%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	24
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	24
	Number of completed questionnaires	27	23
	Return Rate[a]	100%	95.8%
	Return Rate[b]	14.1%	12.5%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	23
	Number of completed questionnaires	26	23
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	12.5%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	19
	Number of completed questionnaires	25	18
	Return Rate[a]	100%	94.7%
	Return Rate[b]	13.0%	9.8%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	16
	Number of completed questionnaires	23	16
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	8.7%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
END OF TREATMENT	Number of subjects expected to complete	170	161
	Number of completed questionnaires	130	135
	Return Rate[a]	76.5%	83.9%
	Return Rate[b]	67.7%	73.4%
SAFETY FOLLOW-UP	Number of subjects expected to complete	106	118
	Number of completed questionnaires	92	99
	Return Rate[a]	86.8%	83.9%
	Return Rate[b]	47.9%	53.8%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	59
	Number of completed questionnaires	49	59
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.1%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	48
	Number of completed questionnaires	48	48
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.1%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	45
	Number of completed questionnaires	42	45
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	24.5%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	35	26
	Number of completed questionnaires	35	26
	Return Rate[a]	100%	100%
	Return Rate[b]	18.2%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	22
	Number of completed questionnaires	29	22
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.0%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	16
	Number of completed questionnaires	19	16
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	8.7%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	2
	Number of completed questionnaires	5	2
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.1%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	40	47
	Return Rate[a]	20.8%	25.5%
	Return Rate[b]	20.8%	25.5%
CYCLE 2 DAY 1	Number of subjects expected to complete	36	45
	Number of completed questionnaires	33	37
	Return Rate[a]	91.7%	82.2%
	Return Rate[b]	17.2%	20.1%
CYCLE 3 DAY 1	Number of subjects expected to complete	43	41
	Number of completed questionnaires	41	38
	Return Rate[a]	95.3%	92.7%
	Return Rate[b]	21.4%	20.7%
CYCLE 4 DAY 1	Number of subjects expected to complete	42	38
	Number of completed questionnaires	40	35
	Return Rate[a]	95.2%	92.1%
	Return Rate[b]	20.8%	19.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	33	43
	Number of completed questionnaires	31	38
	Return Rate[a]	93.9%	88.4%
	Return Rate[b]	16.1%	20.7%
CYCLE 6 DAY 1	Number of subjects expected to complete	32	38
	Number of completed questionnaires	32	34
	Return Rate[a]	100%	89.5%
	Return Rate[b]	16.7%	18.5%
CYCLE 7 DAY 1	Number of subjects expected to complete	32	25
	Number of completed questionnaires	28	24
	Return Rate[a]	87.5%	96.0%
	Return Rate[b]	14.6%	13.0%
CYCLE 8 DAY 1	Number of subjects expected to complete	35	31
	Number of completed questionnaires	33	26
	Return Rate[a]	94.3%	83.9%
	Return Rate[b]	17.2%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
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Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	38	27
	Number of completed questionnaires	37	25
	Return Rate[a]	97.4%	92.6%
	Return Rate[b]	19.3%	13.6%
CYCLE 10 DAY 1	Number of subjects expected to complete	29	23
	Number of completed questionnaires	28	22
	Return Rate[a]	96.6%	95.7%
	Return Rate[b]	14.6%	12.0%
CYCLE 11 DAY 1	Number of subjects expected to complete	25	17
	Number of completed questionnaires	23	16
	Return Rate[a]	92.0%	94.1%
	Return Rate[b]	12.0%	8.7%
CYCLE 12 DAY 1	Number of subjects expected to complete	21	17
	Number of completed questionnaires	21	16
	Return Rate[a]	100%	94.1%
	Return Rate[b]	10.9%	8.7%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	14	11
	Number of completed questionnaires	14	9
	Return Rate[a]	100%	81.8%
	Return Rate[b]	7.3%	4.9%
CYCLE 14 DAY 1	Number of subjects expected to complete	17	10
	Number of completed questionnaires	15	9
	Return Rate[a]	88.2%	90.0%
	Return Rate[b]	7.8%	4.9%
CYCLE 15 DAY 1	Number of subjects expected to complete	16	9
	Number of completed questionnaires	16	8
	Return Rate[a]	100%	88.9%
	Return Rate[b]	8.3%	4.3%
CYCLE 16 DAY 1	Number of subjects expected to complete	12	8
	Number of completed questionnaires	11	8
	Return Rate[a]	91.7%	100%
	Return Rate[b]	5.7%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
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Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	17	7
	Number of completed questionnaires	16	6
	Return Rate[a]	94.1%	85.7%
	Return Rate[b]	8.3%	3.3%
CYCLE 18 DAY 1	Number of subjects expected to complete	10	7
	Number of completed questionnaires	10	6
	Return Rate[a]	100%	85.7%
	Return Rate[b]	5.2%	3.3%
CYCLE 19 DAY 1	Number of subjects expected to complete	11	8
	Number of completed questionnaires	10	8
	Return Rate[a]	90.9%	100%
	Return Rate[b]	5.2%	4.3%
CYCLE 20 DAY 1	Number of subjects expected to complete	7	8
	Number of completed questionnaires	7	8
	Return Rate[a]	100%	100%
	Return Rate[b]	3.6%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	8	8
	Number of completed questionnaires	7	8
	Return Rate[a]	87.5%	100%
	Return Rate[b]	3.6%	4.3%
CYCLE 23 DAY 1	Number of subjects expected to complete	9	7
	Number of completed questionnaires	9	7
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	3.8%
CYCLE 24 DAY 1	Number of subjects expected to complete	8	7
	Number of completed questionnaires	8	7
	Return Rate[a]	100%	100%
	Return Rate[b]	4.2%	3.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	7
	Return Rate[a]	100%	87.5%
	Return Rate[b]	5.2%	3.8%
CYCLE 26 DAY 1	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%
CYCLE 27 DAY 1	Number of subjects expected to complete	9	9
	Number of completed questionnaires	9	8
	Return Rate[a]	100%	88.9%
	Return Rate[b]	4.7%	4.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	8	8
	Number of completed questionnaires	8	8
	Return Rate[a]	100%	100%
	Return Rate[b]	4.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	7	7
	Number of completed questionnaires	7	7
	Return Rate[a]	100%	100%
	Return Rate[b]	3.6%	3.8%
CYCLE 30 DAY 1	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
CYCLE 31 DAY 1	Number of subjects expected to complete	3	4
	Number of completed questionnaires	3	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.6%	2.2%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	1
	Number of completed questionnaires	2	1
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	68	54
	Number of completed questionnaires	27	27
	Return Rate[a]	39.7%	50.0%
	Return Rate[b]	14.1%	14.7%
SAFETY FOLLOW-UP	Number of subjects expected to complete	32	37
	Number of completed questionnaires	18	18
	Return Rate[a]	56.3%	48.6%
	Return Rate[b]	9.4%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	8	11
	Number of completed questionnaires	8	11
	Return Rate[a]	100%	100%
	Return Rate[b]	4.2%	6.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	11	4
	Number of completed questionnaires	11	4
	Return Rate[a]	100%	100%
	Return Rate[b]	5.7%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	9	4
	Number of completed questionnaires	9	4
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	8	7
	Number of completed questionnaires	8	7
	Return Rate[a]	100%	100%
	Return Rate[b]	4.2%	3.8%
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
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Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	8	3
	Number of completed questionnaires	8	3
	Return Rate[a]	100%	100%
	Return Rate[b]	4.2%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	2	3
	Number of completed questionnaires	2	3
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	1	1
	Number of completed questionnaires	1	1
	Return Rate[a]	100%	100%
	Return Rate[b]	0.5%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	184	173
	Return Rate[a]	95.8%	94.0%
	Return Rate[b]	95.8%	94.0%
CYCLE 2 DAY 1	Number of subjects expected to complete	181	177
	Number of completed questionnaires	178	173
	Return Rate[a]	98.3%	97.7%
	Return Rate[b]	92.7%	94.0%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	169
	Number of completed questionnaires	174	167
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.6%	90.8%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	163
	Number of completed questionnaires	169	161
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	87.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	158
	Number of completed questionnaires	161	153
	Return Rate[a]	99.4%	96.8%
	Return Rate[b]	83.9%	83.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	155	155
	Number of completed questionnaires	155	152
	Return Rate[a]	100%	98.1%
	Return Rate[b]	80.7%	82.6%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.7%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	92	78
	Return Rate[a]	98.9%	98.7%
	Return Rate[b]	47.9%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	76	63
	Return Rate[a]	97.4%	98.4%
	Return Rate[b]	39.6%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	65	55
	Number of completed questionnaires	65	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	33.9%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	58	44
	Number of completed questionnaires	58	42
	Return Rate[a]	100%	95.5%
	Return Rate[b]	30.2%	22.8%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	27	29
	Number of completed questionnaires	27	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	27	28
	Number of completed questionnaires	27	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	26	25
	Number of completed questionnaires	26	25
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	25	24
	Number of completed questionnaires	25	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.0%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	24	20
	Number of completed questionnaires	24	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	12.5%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
END OF TREATMENT	Number of subjects expected to complete	170	162
	Number of completed questionnaires	130	136
	Return Rate[a]	76.5%	84.0%
	Return Rate[b]	67.7%	73.9%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	22
	Number of completed questionnaires	29	22
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.0%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	16
	Number of completed questionnaires	19	16
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	8.7%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	2
	Number of completed questionnaires	5	2
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.1%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	174
	Return Rate[a]	96.9%	94.6%
	Return Rate[b]	96.9%	94.6%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	180	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.8%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	170
	Number of completed questionnaires	174	168
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.6%	91.3%
CYCLE 4 DAY 1	Number of subjects expected to complete	169	162
	Number of completed questionnaires	167	160
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	87.0%	87.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	161	159
	Number of completed questionnaires	160	154
	Return Rate[a]	99.4%	96.9%
	Return Rate[b]	83.3%	83.7%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	156
	Number of completed questionnaires	156	153
	Return Rate[a]	100%	98.1%
	Return Rate[b]	81.3%	83.2%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	119	117
	Number of completed questionnaires	117	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	60.9%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.7%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	92	78
	Return Rate[a]	98.9%	98.7%
	Return Rate[b]	47.9%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	76	63
	Return Rate[a]	97.4%	98.4%
	Return Rate[b]	39.6%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	45
	Number of completed questionnaires	59	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.7%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	33
	Number of completed questionnaires	45	32
	Return Rate[a]	97.8%	97.0%
	Return Rate[b]	23.4%	17.4%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	27	29
	Number of completed questionnaires	27	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	24	20
	Number of completed questionnaires	24	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	12.5%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
END OF TREATMENT	Number of subjects expected to complete	171	162
	Number of completed questionnaires	131	136
	Return Rate[a]	76.6%	84.0%
	Return Rate[b]	68.2%	73.9%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	36	25
	Number of completed questionnaires	36	25
	Return Rate[a]	100%	100%
	Return Rate[b]	18.8%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	22
	Number of completed questionnaires	29	22
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.0%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	16
	Number of completed questionnaires	19	16
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	8.7%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	2
	Number of completed questionnaires	5	2
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.1%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	174
	Return Rate[a]	96.9%	94.6%
	Return Rate[b]	96.9%	94.6%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	180	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.8%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	175	170
	Number of completed questionnaires	173	168
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.1%	91.3%
CYCLE 4 DAY 1	Number of subjects expected to complete	169	162
	Number of completed questionnaires	167	160
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	87.0%	87.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	154
	Return Rate[a]	99.4%	96.9%
	Return Rate[b]	83.9%	83.7%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	156
	Number of completed questionnaires	156	153
	Return Rate[a]	100%	98.1%
	Return Rate[b]	81.3%	83.2%
CYCLE 7 DAY 1	Number of subjects expected to complete	144	136
	Number of completed questionnaires	140	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	72.9%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.7%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	92	79
	Number of completed questionnaires	91	78
	Return Rate[a]	98.9%	98.7%
	Return Rate[b]	47.4%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	76	63
	Return Rate[a]	97.4%	98.4%
	Return Rate[b]	39.6%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	44
	Number of completed questionnaires	59	42
	Return Rate[a]	100%	95.5%
	Return Rate[b]	30.7%	22.8%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	27	29
	Number of completed questionnaires	27	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
END OF TREATMENT	Number of subjects expected to complete	171	162
	Number of completed questionnaires	131	136
	Return Rate[a]	76.6%	84.0%
	Return Rate[b]	68.2%	73.9%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	48
	Number of completed questionnaires	48	48
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.1%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	36	26
	Number of completed questionnaires	36	26
	Return Rate[a]	100%	100%
	Return Rate[b]	18.8%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	22
	Number of completed questionnaires	29	22
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.0%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	16
	Number of completed questionnaires	19	16
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	8.7%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	2
	Number of completed questionnaires	5	2
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.1%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	185	174
	Return Rate[a]	96.4%	94.6%
	Return Rate[b]	96.4%	94.6%
CYCLE 2 DAY 1	Number of subjects expected to complete	182	177
	Number of completed questionnaires	179	173
	Return Rate[a]	98.4%	97.7%
	Return Rate[b]	93.2%	94.0%
CYCLE 3 DAY 1	Number of subjects expected to complete	174	170
	Number of completed questionnaires	172	168
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	89.6%	91.3%
CYCLE 4 DAY 1	Number of subjects expected to complete	169	162
	Number of completed questionnaires	167	160
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	87.0%	87.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	159	157
	Number of completed questionnaires	158	152
	Return Rate[a]	99.4%	96.8%
	Return Rate[b]	82.3%	82.6%
CYCLE 6 DAY 1	Number of subjects expected to complete	155	156
	Number of completed questionnaires	155	153
	Return Rate[a]	100%	98.1%
	Return Rate[b]	80.7%	83.2%
CYCLE 7 DAY 1	Number of subjects expected to complete	142	135
	Number of completed questionnaires	138	134
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	71.9%	72.8%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	115
	Number of completed questionnaires	118	111
	Return Rate[a]	98.3%	96.5%
	Return Rate[b]	61.5%	60.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	102
	Number of completed questionnaires	107	100
	Return Rate[a]	99.1%	98.0%
	Return Rate[b]	55.7%	54.3%
CYCLE 10 DAY 1	Number of subjects expected to complete	92	79
	Number of completed questionnaires	91	78
	Return Rate[a]	98.9%	98.7%
	Return Rate[b]	47.4%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	63
	Number of completed questionnaires	76	62
	Return Rate[a]	97.4%	98.4%
	Return Rate[b]	39.6%	33.7%
CYCLE 12 DAY 1	Number of subjects expected to complete	65	55
	Number of completed questionnaires	65	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	33.9%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	44
	Number of completed questionnaires	59	42
	Return Rate[a]	100%	95.5%
	Return Rate[b]	30.7%	22.8%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	27	29
	Number of completed questionnaires	27	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
END OF TREATMENT	Number of subjects expected to complete	171	159
	Number of completed questionnaires	131	133
	Return Rate[a]	76.6%	83.6%
	Return Rate[b]	68.2%	72.3%
SAFETY FOLLOW-UP	Number of subjects expected to complete	105	119
	Number of completed questionnaires	91	100
	Return Rate[a]	86.7%	84.0%
	Return Rate[b]	47.4%	54.3%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	41	46
	Number of completed questionnaires	41	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.4%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	36	26
	Number of completed questionnaires	36	26
	Return Rate[a]	100%	100%
	Return Rate[b]	18.8%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	22
	Number of completed questionnaires	29	22
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.0%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	16
	Number of completed questionnaires	19	16
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	8.7%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	2
	Number of completed questionnaires	5	2
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.1%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	186	174
	Return Rate[a]	96.9%	94.6%
	Return Rate[b]	96.9%	94.6%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	180	174
	Return Rate[a]	98.4%	97.8%
	Return Rate[b]	93.8%	94.6%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	170
	Number of completed questionnaires	174	168
	Return Rate[a]	98.9%	98.8%
	Return Rate[b]	90.6%	91.3%
CYCLE 4 DAY 1	Number of subjects expected to complete	169	163
	Number of completed questionnaires	167	161
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	87.0%	87.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	154
	Return Rate[a]	99.4%	96.9%
	Return Rate[b]	83.9%	83.7%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	157
	Number of completed questionnaires	156	154
	Return Rate[a]	100%	98.1%
	Return Rate[b]	81.3%	83.7%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	116
	Number of completed questionnaires	118	112
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	60.9%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	102
	Return Rate[a]	99.1%	98.1%
	Return Rate[b]	55.7%	55.4%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	92	78
	Return Rate[a]	98.9%	98.7%
	Return Rate[b]	47.9%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	76	63
	Return Rate[a]	97.4%	98.4%
	Return Rate[b]	39.6%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	66	54
	Return Rate[a]	100%	98.2%
	Return Rate[b]	34.4%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	44
	Number of completed questionnaires	59	42
	Return Rate[a]	100%	95.5%
	Return Rate[b]	30.7%	22.8%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	55	42
	Return Rate[a]	96.5%	97.7%
	Return Rate[b]	28.6%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	27	29
	Number of completed questionnaires	27	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	4	7
	Number of completed questionnaires	4	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
END OF TREATMENT	Number of subjects expected to complete	171	161
	Number of completed questionnaires	131	135
	Return Rate[a]	76.6%	83.9%
	Return Rate[b]	68.2%	73.4%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	49
	Number of completed questionnaires	48	49
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.6%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	36	26
	Number of completed questionnaires	36	26
	Return Rate[a]	100%	100%
	Return Rate[b]	18.8%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	22
	Number of completed questionnaires	29	22
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.0%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	19	16
	Number of completed questionnaires	19	16
	Return Rate[a]	100%	100%
	Return Rate[b]	9.9%	8.7%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.2302 Summary of Return Rates in EORTC-QLQ-EN24 by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	2
	Number of completed questionnaires	5	2
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.1%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_2302_en24_return.sas, Output: t_2_2302_en24_return.rtf, Generated on: 30AUG2024 13:44,
Data Cutoff Date: 22SEP2023

Table 2.3002 Summary of Return Rates in EQ-5D-5L Visual Analogue Scores by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
BASELINE	Number of subjects expected to complete	192	184
	Number of completed questionnaires	185	176
	Return Rate[a]	96.4%	95.7%
	Return Rate[b]	96.4%	95.7%
CYCLE 2 DAY 1	Number of subjects expected to complete	183	178
	Number of completed questionnaires	179	172
	Return Rate[a]	97.8%	96.6%
	Return Rate[b]	93.2%	93.5%
CYCLE 3 DAY 1	Number of subjects expected to complete	176	170
	Number of completed questionnaires	173	167
	Return Rate[a]	98.3%	98.2%
	Return Rate[b]	90.1%	90.8%
CYCLE 4 DAY 1	Number of subjects expected to complete	171	164
	Number of completed questionnaires	169	162
	Return Rate[a]	98.8%	98.8%
	Return Rate[b]	88.0%	88.0%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_3002_eq5d_return.sas, Output: t_2_3002_eq5d_return.rtf, Generated on: 30AUG2024 13:46,
Data Cutoff Date: 22SEP2023

Table 2.3002 Summary of Return Rates in EQ-5D-5L Visual Analogue Scores by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 5 DAY 1	Number of subjects expected to complete	162	159
	Number of completed questionnaires	161	155
	Return Rate[a]	99.4%	97.5%
	Return Rate[b]	83.9%	84.2%
CYCLE 6 DAY 1	Number of subjects expected to complete	156	157
	Number of completed questionnaires	155	154
	Return Rate[a]	99.4%	98.1%
	Return Rate[b]	80.7%	83.7%
CYCLE 7 DAY 1	Number of subjects expected to complete	145	136
	Number of completed questionnaires	141	135
	Return Rate[a]	97.2%	99.3%
	Return Rate[b]	73.4%	73.4%
CYCLE 8 DAY 1	Number of subjects expected to complete	120	117
	Number of completed questionnaires	118	113
	Return Rate[a]	98.3%	96.6%
	Return Rate[b]	61.5%	61.4%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_3002_eq5d_return.sas, Output: t_2_3002_eq5d_return.rtf, Generated on: 30AUG2024 13:46,
Data Cutoff Date: 22SEP2023

Table 2.3002 Summary of Return Rates in EQ-5D-5L Visual Analogue Scores by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 9 DAY 1	Number of subjects expected to complete	108	104
	Number of completed questionnaires	107	101
	Return Rate[a]	99.1%	97.1%
	Return Rate[b]	55.7%	54.9%
CYCLE 10 DAY 1	Number of subjects expected to complete	93	79
	Number of completed questionnaires	93	78
	Return Rate[a]	100%	98.7%
	Return Rate[b]	48.4%	42.4%
CYCLE 11 DAY 1	Number of subjects expected to complete	78	64
	Number of completed questionnaires	76	63
	Return Rate[a]	97.4%	98.4%
	Return Rate[b]	39.6%	34.2%
CYCLE 12 DAY 1	Number of subjects expected to complete	66	55
	Number of completed questionnaires	65	54
	Return Rate[a]	98.5%	98.2%
	Return Rate[b]	33.9%	29.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_3002_eq5d_return.sas, Output: t_2_3002_eq5d_return.rtf, Generated on: 30AUG2024 13:46,
Data Cutoff Date: 22SEP2023

Table 2.3002 Summary of Return Rates in EQ-5D-5L Visual Analogue Scores by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 13 DAY 1	Number of subjects expected to complete	59	45
	Number of completed questionnaires	59	43
	Return Rate[a]	100%	95.6%
	Return Rate[b]	30.7%	23.4%
CYCLE 14 DAY 1	Number of subjects expected to complete	57	43
	Number of completed questionnaires	56	42
	Return Rate[a]	98.2%	97.7%
	Return Rate[b]	29.2%	22.8%
CYCLE 15 DAY 1	Number of subjects expected to complete	51	40
	Number of completed questionnaires	51	39
	Return Rate[a]	100%	97.5%
	Return Rate[b]	26.6%	21.2%
CYCLE 16 DAY 1	Number of subjects expected to complete	47	37
	Number of completed questionnaires	46	37
	Return Rate[a]	97.9%	100%
	Return Rate[b]	24.0%	20.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_3002_eq5d_return.sas, Output: t_2_3002_eq5d_return.rtf, Generated on: 30AUG2024 13:46,
Data Cutoff Date: 22SEP2023

Table 2.3002 Summary of Return Rates in EQ-5D-5L Visual Analogue Scores by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 17 DAY 1	Number of subjects expected to complete	46	34
	Number of completed questionnaires	45	33
	Return Rate[a]	97.8%	97.1%
	Return Rate[b]	23.4%	17.9%
CYCLE 18 DAY 1	Number of subjects expected to complete	35	34
	Number of completed questionnaires	35	33
	Return Rate[a]	100%	97.1%
	Return Rate[b]	18.2%	17.9%
CYCLE 19 DAY 1	Number of subjects expected to complete	33	32
	Number of completed questionnaires	33	32
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	17.4%
CYCLE 20 DAY 1	Number of subjects expected to complete	33	31
	Number of completed questionnaires	33	31
	Return Rate[a]	100%	100%
	Return Rate[b]	17.2%	16.8%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_3002_eq5d_return.sas, Output: t_2_3002_eq5d_return.rtf, Generated on: 30AUG2024 13:46,
Data Cutoff Date: 22SEP2023

Table 2.3002 Summary of Return Rates in EQ-5D-5L Visual Analogue Scores by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 21 DAY 1	Number of subjects expected to complete	30	30
	Number of completed questionnaires	30	30
	Return Rate[a]	100%	100%
	Return Rate[b]	15.6%	16.3%
CYCLE 22 DAY 1	Number of subjects expected to complete	28	29
	Number of completed questionnaires	28	29
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.8%
CYCLE 23 DAY 1	Number of subjects expected to complete	28	28
	Number of completed questionnaires	28	28
	Return Rate[a]	100%	100%
	Return Rate[b]	14.6%	15.2%
CYCLE 24 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	25
	Return Rate[a]	100%	100%
	Return Rate[b]	14.1%	13.6%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_3002_eq5d_return.sas, Output: t_2_3002_eq5d_return.rtf, Generated on: 30AUG2024 13:46,
Data Cutoff Date: 22SEP2023

Table 2.3002 Summary of Return Rates in EQ-5D-5L Visual Analogue Scores by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 25 DAY 1	Number of subjects expected to complete	27	25
	Number of completed questionnaires	27	24
	Return Rate[a]	100%	96.0%
	Return Rate[b]	14.1%	13.0%
CYCLE 26 DAY 1	Number of subjects expected to complete	26	24
	Number of completed questionnaires	26	24
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	13.0%
CYCLE 27 DAY 1	Number of subjects expected to complete	25	20
	Number of completed questionnaires	25	19
	Return Rate[a]	100%	95.0%
	Return Rate[b]	13.0%	10.3%
CYCLE 28 DAY 1	Number of subjects expected to complete	23	17
	Number of completed questionnaires	23	17
	Return Rate[a]	100%	100%
	Return Rate[b]	12.0%	9.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_3002_eq5d_return.sas, Output: t_2_3002_eq5d_return.rtf, Generated on: 30AUG2024 13:46,
Data Cutoff Date: 22SEP2023

Table 2.3002 Summary of Return Rates in EQ-5D-5L Visual Analogue Scores by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 29 DAY 1	Number of subjects expected to complete	13	14
	Number of completed questionnaires	13	14
	Return Rate[a]	100%	100%
	Return Rate[b]	6.8%	7.6%
CYCLE 30 DAY 1	Number of subjects expected to complete	9	10
	Number of completed questionnaires	9	10
	Return Rate[a]	100%	100%
	Return Rate[b]	4.7%	5.4%
CYCLE 31 DAY 1	Number of subjects expected to complete	5	7
	Number of completed questionnaires	5	7
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	3.8%
CYCLE 32 DAY 1	Number of subjects expected to complete	2	4
	Number of completed questionnaires	2	4
	Return Rate[a]	100%	100%
	Return Rate[b]	1.0%	2.2%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_3002_eq5d_return.sas, Output: t_2_3002_eq5d_return.rtf, Generated on: 30AUG2024 13:46,
Data Cutoff Date: 22SEP2023

Table 2.3002 Summary of Return Rates in EQ-5D-5L Visual Analogue Scores by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
CYCLE 33 DAY 1	Number of subjects expected to complete	0	2
	Number of completed questionnaires	0	2
	Return Rate[a]	-	100%
	Return Rate[b]	0	1.1%
CYCLE 34 DAY 1	Number of subjects expected to complete	0	1
	Number of completed questionnaires	0	1
	Return Rate[a]	-	100%
	Return Rate[b]	0	0.5%
END OF TREATMENT	Number of subjects expected to complete	171	162
	Number of completed questionnaires	131	136
	Return Rate[a]	76.6%	84.0%
	Return Rate[b]	68.2%	73.9%
SAFETY FOLLOW-UP	Number of subjects expected to complete	107	119
	Number of completed questionnaires	93	100
	Return Rate[a]	86.9%	84.0%
	Return Rate[b]	48.4%	54.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_3002_eq5d_return.sas, Output: t_2_3002_eq5d_return.rtf, Generated on: 30AUG2024 13:46,
Data Cutoff Date: 22SEP2023

Table 2.3002 Summary of Return Rates in EQ-5D-5L Visual Analogue Scores by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 1	Number of subjects expected to complete	49	60
	Number of completed questionnaires	49	60
	Return Rate[a]	100%	100%
	Return Rate[b]	25.5%	32.6%
SURVIVAL FOLLOW-UP ASSESSMENT 2	Number of subjects expected to complete	48	48
	Number of completed questionnaires	48	48
	Return Rate[a]	100%	100%
	Return Rate[b]	25.0%	26.1%
SURVIVAL FOLLOW-UP ASSESSMENT 3	Number of subjects expected to complete	42	46
	Number of completed questionnaires	42	46
	Return Rate[a]	100%	100%
	Return Rate[b]	21.9%	25.0%
SURVIVAL FOLLOW-UP ASSESSMENT 4	Number of subjects expected to complete	37	26
	Number of completed questionnaires	37	26
	Return Rate[a]	100%	100%
	Return Rate[b]	19.3%	14.1%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_3002_eq5d_return.sas, Output: t_2_3002_eq5d_return.rtf, Generated on: 30AUG2024 13:46,
Data Cutoff Date: 22SEP2023

Table 2.3002 Summary of Return Rates in EQ-5D-5L Visual Analogue Scores by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 5	Number of subjects expected to complete	29	23
	Number of completed questionnaires	29	23
	Return Rate[a]	100%	100%
	Return Rate[b]	15.1%	12.5%
SURVIVAL FOLLOW-UP ASSESSMENT 6	Number of subjects expected to complete	26	18
	Number of completed questionnaires	26	18
	Return Rate[a]	100%	100%
	Return Rate[b]	13.5%	9.8%
SURVIVAL FOLLOW-UP ASSESSMENT 7	Number of subjects expected to complete	20	16
	Number of completed questionnaires	20	16
	Return Rate[a]	100%	100%
	Return Rate[b]	10.4%	8.7%
SURVIVAL FOLLOW-UP ASSESSMENT 8	Number of subjects expected to complete	10	8
	Number of completed questionnaires	10	8
	Return Rate[a]	100%	100%
	Return Rate[b]	5.2%	4.3%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_3002_eq5d_return.sas, Output: t_2_3002_eq5d_return.rtf, Generated on: 30AUG2024 13:46,
Data Cutoff Date: 22SEP2023

Table 2.3002 Summary of Return Rates in EQ-5D-5L Visual Analogue Scores by Visit (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Visit		Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
SURVIVAL FOLLOW-UP ASSESSMENT 9	Number of subjects expected to complete	5	3
	Number of completed questionnaires	5	3
	Return Rate[a]	100%	100%
	Return Rate[b]	2.6%	1.6%
SURVIVAL FOLLOW-UP ASSESSMENT 10	Number of subjects expected to complete	4	4
	Number of completed questionnaires	4	4
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	2.2%
SURVIVAL FOLLOW-UP ASSESSMENT 11	Number of subjects expected to complete	4	1
	Number of completed questionnaires	4	1
	Return Rate[a]	100%	100%
	Return Rate[b]	2.1%	0.5%

a. Return Rate calculated as (Number of completed questionnaires/Number of subjects expected to complete)*100
b. Return Rate calculated as (Number of completed questionnaires/Number of subjects in each treatment group)*100
Program: t_2_3002_eq5d_return.sas, Output: t_2_3002_eq5d_return.rtf, Generated on: 30AUG2024 13:46,
Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	176 (95.7%)
		LS Mean (SE)	-2.5 (1.00)	-1.9 (1.09)
		95% CI	-4.4, -0.5	-4.0, 0.3
		Difference from placebo		
		LS Mean (SE)	-0.6 (1.50)	
		95% CI	-3.6, 2.3	
		p-value	0.6818	
		Corrected Hedges' g (95% CI)	-0.04 (-0.25, 0.16)	
Week 4	Change from Baseline	n (%)	177 (92.2%)	174 (94.6%)
		LS Mean (SE)	0.3 (1.31)	-0.5 (1.32)
		95% CI	-2.3, 2.9	-3.1, 2.1
		Difference from placebo		
		LS Mean (SE)	0.8 (1.86)	
		95% CI	-2.8, 4.5	
		p-value	0.6553	
		Corrected Hedges' g (95% CI)	0.05 (-0.16, 0.26)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	169 (88.0%)	165 (89.7%)
		LS Mean (SE)	-0.7 (1.33)	1.5 (1.34)
		95% CI	-3.3, 1.9	-1.1, 4.2
		Difference from placebo		
		LS Mean (SE)	-2.3 (1.88)	
		95% CI	-5.9, 1.4	
		p-value	0.2324	
		Corrected Hedges' g (95% CI)	-0.13 (-0.35, 0.08)	
Week 10	Change from Baseline	n (%)	166 (86.5%)	156 (84.8%)
		LS Mean (SE)	-2.1 (1.33)	-1.6 (1.37)
		95% CI	-4.7, 0.5	-4.3, 1.0
		Difference from placebo		
		LS Mean (SE)	-0.5 (1.91)	
		95% CI	-4.2, 3.2	
		p-value	0.7940	
		Corrected Hedges' g (95% CI)	-0.03 (-0.25, 0.19)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	149 (81.0%)
		LS Mean (SE)	-4.0 (1.36)	-1.0 (1.38)
		95% CI	-6.7, -1.3	-3.7, 1.7
		Difference from placebo		
		LS Mean (SE)	-3.0 (1.94)	
		95% CI	-6.8, 0.8	
		p-value	0.1240	
		Corrected Hedges' g (95% CI)	-0.18 (-0.40, 0.05)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	148 (80.4%)
		LS Mean (SE)	-5.8 (1.37)	-1.9 (1.39)
		95% CI	-8.5, -3.1	-4.6, 0.8
		Difference from placebo		
		LS Mean (SE)	-3.9 (1.95)	
		95% CI	-7.7, -0.1	
		p-value	0.0457	
		Corrected Hedges' g (95% CI)	-0.23 (-0.46, -0.00)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	150 (81.5%)
		LS Mean (SE)	-4.8 (1.37)	-2.2 (1.39)
		95% CI	-7.4, -2.1	-5.0, 0.5
		Difference from placebo		
		LS Mean (SE)	-2.5 (1.95)	
		95% CI	-6.3, 1.3	
		p-value	0.1965	
		Corrected Hedges' g (95% CI)	-0.15 (-0.37, 0.08)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	133 (72.3%)
		LS Mean (SE)	-2.8 (1.42)	0.3 (1.44)
		95% CI	-5.5, 0.0	-2.5, 3.2
		Difference from placebo		
		LS Mean (SE)	-3.1 (2.02)	
		95% CI	-7.1, 0.9	
		p-value	0.1261	
		Corrected Hedges' g (95% CI)	-0.19 (-0.42, 0.05)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	127 (66.1%)	132 (71.7%)
		LS Mean (SE)	-0.8 (1.46)	0.5 (1.45)
		95% CI	-3.6, 2.1	-2.4, 3.3
		Difference from placebo		
		LS Mean (SE)	-1.2 (2.06)	
		95% CI	-5.3, 2.8	
		p-value	0.5467	
		Corrected Hedges' g (95% CI)	-0.07 (-0.32, 0.17)	
Week 37	Change from Baseline	n (%)	113 (58.9%)	107 (58.2%)
		LS Mean (SE)	-0.5 (1.52)	0.4 (1.56)
		95% CI	-3.5, 2.5	-2.7, 3.4
		Difference from placebo		
		LS Mean (SE)	-0.9 (2.18)	
		95% CI	-5.2, 3.4	
		p-value	0.6841	
		Corrected Hedges' g (95% CI)	-0.05 (-0.32, 0.21)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	105 (54.7%)	106 (57.6%)
		LS Mean (SE)	0.3 (1.56)	0.2 (1.58)
		95% CI	-2.8, 3.4	-2.9, 3.2
		Difference from placebo		
		LS Mean (SE)	0.1 (2.22)	
		95% CI	-4.2, 4.5	
		p-value	0.9497	
		Corrected Hedges' g (95% CI)	0.01 (-0.26, 0.28)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	83 (45.1%)
		LS Mean (SE)	0.2 (1.63)	-0.4 (1.70)
		95% CI	-3.0, 3.3	-3.8, 2.9
		Difference from placebo		
		LS Mean (SE)	0.6 (2.36)	
		95% CI	-4.0, 5.2	
		p-value	0.8052	
		Corrected Hedges' g (95% CI)	0.04 (-0.26, 0.33)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	90 (46.9%)	83 (45.1%)
		LS Mean (SE)	-1.8 (1.65)	-3.1 (1.71)
		95% CI	-5.1, 1.4	-6.5, 0.3
		Difference from placebo		
		LS Mean (SE)	1.3 (2.38)	
		95% CI	-3.4, 5.9	
		p-value	0.5982	
		Corrected Hedges' g (95% CI)	0.08 (-0.22, 0.38)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	65 (35.3%)
		LS Mean (SE)	-1.4 (1.73)	-0.1 (1.86)
		95% CI	-4.8, 2.0	-3.8, 3.5
		Difference from placebo		
		LS Mean (SE)	-1.2 (2.54)	
		95% CI	-6.2, 3.7	
		p-value	0.6232	
		Corrected Hedges' g (95% CI)	-0.08 (-0.41, 0.25)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	72 (39.1%)
		LS Mean (SE)	-3.1 (1.72)	-0.1 (1.81)
		95% CI	-6.4, 0.3	-3.7, 3.4
		Difference from placebo		
		LS Mean (SE)	-2.9 (2.50)	
		95% CI	-7.8, 2.0	
		p-value	0.2413	
		Corrected Hedges' g (95% CI)	-0.19 (-0.51, 0.13)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	62 (33.7%)
		LS Mean (SE)	-1.5 (1.77)	-3.4 (1.91)
		95% CI	-5.0, 2.0	-7.2, 0.3
		Difference from placebo		
		LS Mean (SE)	1.9 (2.60)	
		95% CI	-3.2, 7.0	
		p-value	0.4613	
		Corrected Hedges' g (95% CI)	0.13 (-0.21, 0.46)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	65 (33.9%)	57 (31.0%)
		LS Mean (SE)	0.4 (1.86)	-1.5 (1.97)
		95% CI	-3.2, 4.0	-5.4, 2.4
		Difference from placebo		
		LS Mean (SE)	1.9 (2.71)	
		95% CI	-3.4, 7.2	
		p-value	0.4825	
		Corrected Hedges' g (95% CI)	0.13 (-0.23, 0.48)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	-0.8 (1.84)	0.3 (1.97)
		95% CI	-4.4, 2.8	-3.6, 4.1
		Difference from placebo		
		LS Mean (SE)	-1.1 (2.70)	
		95% CI	-6.4, 4.2	
		p-value	0.6945	
		Corrected Hedges' g (95% CI)	-0.07 (-0.42, 0.28)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	49 (26.6%)
		LS Mean (SE)	-1.3 (2.01)	-4.0 (2.11)
		95% CI	-5.2, 2.6	-8.1, 0.1
		Difference from placebo		
		LS Mean (SE)	2.7 (2.92)	
		95% CI	-3.0, 8.4	
		p-value	0.3513	
		Corrected Hedges' g (95% CI)	0.18 (-0.21, 0.57)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	-1.7 (1.90)	-3.1 (2.06)
		95% CI	-5.4, 2.0	-7.2, 0.9
		Difference from placebo		
		LS Mean (SE)	1.4 (2.80)	
		95% CI	-4.1, 6.9	
		p-value	0.6228	
		Corrected Hedges' g (95% CI)	0.09 (-0.28, 0.46)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	-1.9 (2.01)	-1.1 (2.21)
		95% CI	-5.8, 2.1	-5.5, 3.2
		Difference from placebo		
		LS Mean (SE)	-0.8 (3.00)	
		95% CI	-6.6, 5.1	
		p-value	0.7975	
		Corrected Hedges' g (95% CI)	-0.05 (-0.45, 0.35)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	-3.8 (2.06)	-0.9 (2.09)
		95% CI	-7.9, 0.2	-5.0, 3.2
		Difference from placebo		
		LS Mean (SE)	-2.9 (2.93)	
		95% CI	-8.7, 2.8	
		p-value	0.3146	
		Corrected Hedges' g (95% CI)	-0.20 (-0.59, 0.19)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	42 (22.8%)
		LS Mean (SE)	-0.1 (2.09)	-3.2 (2.23)
		95% CI	-4.2, 4.0	-7.6, 1.2
		Difference from placebo		
		LS Mean (SE)	3.1 (3.06)	
		95% CI	-2.9, 9.1	
		p-value	0.3085	
		Corrected Hedges' g (95% CI)	0.21 (-0.20, 0.63)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	50 (27.2%)
		LS Mean (SE)	-2.6 (2.08)	-6.7 (2.11)
		95% CI	-6.7, 1.5	-10.8, -2.6
		Difference from placebo		
		LS Mean (SE)	4.1 (2.96)	
		95% CI	-1.7, 9.9	
		p-value	0.1678	
		Corrected Hedges' g (95% CI)	0.27 (-0.12, 0.67)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	43 (23.4%)
		LS Mean (SE)	-1.0 (2.20)	-3.3 (2.22)
		95% CI	-5.3, 3.4	-7.7, 1.0
		Difference from placebo		
		LS Mean (SE)	2.4 (3.14)	
		95% CI	-3.8, 8.5	
		p-value	0.4485	
		Corrected Hedges' g (95% CI)	0.16 (-0.26, 0.58)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	0.8 (2.16)	-4.9 (2.23)
		95% CI	-3.5, 5.0	-9.3, -0.6
		Difference from placebo		
		LS Mean (SE)	5.7 (3.11)	
		95% CI	-0.4, 11.8	
		p-value	0.0671	
		Corrected Hedges' g (95% CI)	0.39 (-0.03, 0.81)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	0.1 (2.20)	-5.6 (2.40)
		95% CI	-4.2, 4.4	-10.3, -0.9
		Difference from placebo		
		LS Mean (SE)	5.7 (3.26)	
		95% CI	-0.7, 12.1	
		p-value	0.0802	
		Corrected Hedges' g (95% CI)	0.39 (-0.05, 0.83)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	-1.3 (2.35)	-0.8 (2.59)
		95% CI	-5.9, 3.3	-5.8, 4.3
		Difference from placebo		
		LS Mean (SE)	-0.5 (3.49)	
		95% CI	-7.4, 6.3	
		p-value	0.8816	
		Corrected Hedges' g (95% CI)	-0.04 (-0.51, 0.44)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	-1.4 (2.44)	-0.3 (2.87)
		95% CI	-6.2, 3.4	-5.9, 5.3
		Difference from placebo		
		LS Mean (SE)	-1.1 (3.78)	
		95% CI	-8.5, 6.3	
		p-value	0.7794	
		Corrected Hedges' g (95% CI)	-0.07 (-0.59, 0.45)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	-2.6 (2.78)	-4.6 (3.06)
		95% CI	-8.0, 2.9	-10.7, 1.4
		Difference from placebo		
		LS Mean (SE)	2.1 (4.14)	
		95% CI	-6.1, 10.2	
		p-value	0.6193	
		Corrected Hedges' g (95% CI)	0.14 (-0.43, 0.72)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	-4.8 (3.06)	-1.2 (3.38)
		95% CI	-10.8, 1.2	-7.9, 5.4
		Difference from placebo		
		LS Mean (SE)	-3.5 (4.57)	
		95% CI	-12.5, 5.4	
		p-value	0.4426	
		Corrected Hedges' g (95% CI)	-0.25 (-0.89, 0.40)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	-2.1 (3.38)	-1.8 (4.18)
		95% CI	-8.7, 4.5	-10.0, 6.4
		Difference from placebo		
		LS Mean (SE)	-0.3 (5.37)	
		95% CI	-10.8, 10.2	
		p-value	0.9530	
		Corrected Hedges' g (95% CI)	-0.02 (-0.78, 0.74)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	-12.5 (4.06)	-4.6 (4.35)
		95% CI	-20.5, -4.6	-13.1, 4.0
		Difference from placebo		
		LS Mean (SE)	-7.9 (6.06)	
		95% CI	-19.8, 4.0	
		p-value	0.1906	
		Corrected Hedges' g (95% CI)	-0.54 (-1.37, 0.30)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	-13.8 (4.65)	6.5 (5.45)
		95% CI	-22.9, -4.7	-4.2, 17.1
		Difference from placebo		
		LS Mean (SE)	-20.2 (6.98)	
		95% CI	-33.9, -6.6	
		p-value	0.0038	
		Corrected Hedges' g (95% CI)	-1.31 (-2.36, -0.26)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	-5.5 (6.99)	-10.8 (13.05)
		95% CI	-19.2, 8.2	-36.3, 14.8
		Difference from placebo		
		LS Mean (SE)	5.2 (16.73)	
		95% CI	-27.6, 38.0	
		p-value	0.7545	
		Corrected Hedges' g (95% CI)	0.27 (-1.37, 1.92)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	180 (93.8%)	176 (95.7%)
		LS Mean (SE)	-7.4 (1.07)	-5.1 (1.19)
		95% CI	-9.5, -5.3	-7.4, -2.7
		Difference from placebo		
		LS Mean (SE)	-2.4 (1.59)	
		95% CI	-5.5, 0.8	
		p-value	0.1398	
		Corrected Hedges' g (95% CI)	-0.16 (-0.36, 0.05)	
Week 4	Change from Baseline	n (%)	176 (91.7%)	174 (94.6%)
		LS Mean (SE)	-3.3 (1.35)	-0.2 (1.37)
		95% CI	-6.0, -0.6	-2.8, 2.5
		Difference from placebo		
		LS Mean (SE)	-3.1 (1.92)	
		95% CI	-6.9, 0.6	
		p-value	0.1017	
		Corrected Hedges' g (95% CI)	-0.17 (-0.38, 0.04)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	169 (88.0%)	164 (89.1%)
		LS Mean (SE)	-4.6 (1.36)	-1.7 (1.38)
		95% CI	-7.3, -2.0	-4.4, 1.0
		Difference from placebo		
		LS Mean (SE)	-2.9 (1.93)	
		95% CI	-6.7, 0.9	
		p-value	0.1358	
		Corrected Hedges' g (95% CI)	-0.16 (-0.38, 0.05)	
Week 10	Change from Baseline	n (%)	165 (85.9%)	155 (84.2%)
		LS Mean (SE)	-6.2 (1.37)	-3.9 (1.40)
		95% CI	-8.9, -3.5	-6.7, -1.2
		Difference from placebo		
		LS Mean (SE)	-2.3 (1.95)	
		95% CI	-6.1, 1.5	
		p-value	0.2423	
		Corrected Hedges' g (95% CI)	-0.13 (-0.35, 0.09)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	156 (81.3%)	148 (80.4%)
		LS Mean (SE)	-7.5 (1.38)	-6.4 (1.41)
		95% CI	-10.2, -4.7	-9.1, -3.6
		Difference from placebo		
		LS Mean (SE)	-1.1 (1.97)	
		95% CI	-5.0, 2.8	
		p-value	0.5754	
		Corrected Hedges' g (95% CI)	-0.06 (-0.29, 0.16)	
Week 16	Change from Baseline	n (%)	151 (78.6%)	149 (81.0%)
		LS Mean (SE)	-9.9 (1.40)	-7.5 (1.42)
		95% CI	-12.6, -7.2	-10.3, -4.7
		Difference from placebo		
		LS Mean (SE)	-2.4 (1.99)	
		95% CI	-6.3, 1.5	
		p-value	0.2269	
		Corrected Hedges' g (95% CI)	-0.14 (-0.37, 0.09)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	152 (79.2%)	149 (81.0%)
		LS Mean (SE)	-10.0 (1.40)	-7.8 (1.42)
		95% CI	-12.8, -7.3	-10.6, -5.0
		Difference from placebo		
		LS Mean (SE)	-2.2 (2.00)	
		95% CI	-6.1, 1.7	
		p-value	0.2694	
		Corrected Hedges' g (95% CI)	-0.13 (-0.35, 0.10)	
Week 25	Change from Baseline	n (%)	137 (71.4%)	132 (71.7%)
		LS Mean (SE)	-8.4 (1.44)	-4.1 (1.46)
		95% CI	-11.2, -5.5	-6.9, -1.2
		Difference from placebo		
		LS Mean (SE)	-4.3 (2.05)	
		95% CI	-8.3, -0.3	
		p-value	0.0360	
		Corrected Hedges' g (95% CI)	-0.26 (-0.50, -0.02)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	125 (65.1%)	132 (71.7%)
		LS Mean (SE)	-7.2 (1.48)	-4.8 (1.48)
		95% CI	-10.1, -4.3	-7.7, -1.9
		Difference from placebo		
		LS Mean (SE)	-2.3 (2.09)	
		95% CI	-6.4, 1.8	
		p-value	0.2625	
		Corrected Hedges' g (95% CI)	-0.14 (-0.38, 0.11)	
Week 37	Change from Baseline	n (%)	113 (58.9%)	105 (57.1%)
		LS Mean (SE)	-3.6 (1.53)	-3.3 (1.56)
		95% CI	-6.6, -0.6	-6.3, -0.2
		Difference from placebo		
		LS Mean (SE)	-0.4 (2.18)	
		95% CI	-4.6, 3.9	
		p-value	0.8697	
		Corrected Hedges' g (95% CI)	-0.02 (-0.29, 0.24)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	102 (53.1%)	106 (57.6%)
		LS Mean (SE)	-3.9 (1.58)	-2.7 (1.59)
		95% CI	-7.0, -0.8	-5.8, 0.4
		Difference from placebo		
		LS Mean (SE)	-1.3 (2.24)	
		95% CI	-5.6, 3.1	
		p-value	0.5740	
		Corrected Hedges' g (95% CI)	-0.08 (-0.35, 0.19)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	83 (45.1%)
		LS Mean (SE)	-5.7 (1.63)	-3.2 (1.68)
		95% CI	-8.9, -2.5	-6.5, 0.1
		Difference from placebo		
		LS Mean (SE)	-2.5 (2.34)	
		95% CI	-7.1, 2.1	
		p-value	0.2873	
		Corrected Hedges' g (95% CI)	-0.16 (-0.46, 0.14)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	89 (46.4%)	83 (45.1%)
		LS Mean (SE)	-6.2 (1.66)	-6.1 (1.71)
		95% CI	-9.5, -3.0	-9.4, -2.7
		Difference from placebo		
		LS Mean (SE)	-0.2 (2.38)	
		95% CI	-4.8, 4.5	
		p-value	0.9456	
		Corrected Hedges' g (95% CI)	-0.01 (-0.31, 0.29)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	64 (34.8%)
		LS Mean (SE)	-4.9 (1.72)	-4.5 (1.82)
		95% CI	-8.3, -1.5	-8.0, -0.9
		Difference from placebo		
		LS Mean (SE)	-0.4 (2.50)	
		95% CI	-5.3, 4.5	
		p-value	0.8666	
		Corrected Hedges' g (95% CI)	-0.03 (-0.36, 0.30)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	72 (39.1%)
		LS Mean (SE)	-7.3 (1.72)	-5.0 (1.80)
		95% CI	-10.6, -3.9	-8.6, -1.5
		Difference from placebo		
		LS Mean (SE)	-2.2 (2.49)	
		95% CI	-7.1, 2.6	
		p-value	0.3689	
		Corrected Hedges' g (95% CI)	-0.15 (-0.46, 0.17)	
Week 73	Change from Baseline	n (%)	72 (37.5%)	62 (33.7%)
		LS Mean (SE)	-6.2 (1.78)	-5.9 (1.88)
		95% CI	-9.7, -2.7	-9.6, -2.2
		Difference from placebo		
		LS Mean (SE)	-0.3 (2.58)	
		95% CI	-5.4, 4.7	
		p-value	0.8942	
		Corrected Hedges' g (95% CI)	-0.02 (-0.36, 0.32)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	65 (33.9%)	57 (31.0%)
		LS Mean (SE)	-4.7 (1.84)	-7.2 (1.94)
		95% CI	-8.3, -1.1	-11.0, -3.4
		Difference from placebo		
		LS Mean (SE)	2.5 (2.67)	
		95% CI	-2.7, 7.7	
		p-value	0.3488	
		Corrected Hedges' g (95% CI)	0.17 (-0.19, 0.53)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	-7.3 (1.84)	-3.6 (1.95)
		95% CI	-10.9, -3.7	-7.4, 0.3
		Difference from placebo		
		LS Mean (SE)	-3.7 (2.69)	
		95% CI	-9.0, 1.5	
		p-value	0.1650	
		Corrected Hedges' g (95% CI)	-0.25 (-0.60, 0.11)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	48 (26.1%)
		LS Mean (SE)	-8.9 (1.96)	-5.4 (2.07)
		95% CI	-12.7, -5.1	-9.5, -1.4
		Difference from placebo		
		LS Mean (SE)	-3.5 (2.85)	
		95% CI	-9.1, 2.1	
		p-value	0.2197	
		Corrected Hedges' g (95% CI)	-0.24 (-0.63, 0.15)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	-7.3 (1.90)	-4.4 (2.06)
		95% CI	-11.0, -3.6	-8.4, -0.4
		Difference from placebo		
		LS Mean (SE)	-2.9 (2.79)	
		95% CI	-8.4, 2.6	
		p-value	0.3014	
		Corrected Hedges' g (95% CI)	-0.19 (-0.56, 0.18)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	-7.4 (1.98)	-5.8 (2.16)
		95% CI	-11.2, -3.5	-10.0, -1.6
		Difference from placebo		
		LS Mean (SE)	-1.6 (2.93)	
		95% CI	-7.3, 4.2	
		p-value	0.5949	
		Corrected Hedges' g (95% CI)	-0.11 (-0.51, 0.29)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	-7.0 (2.03)	-5.7 (2.09)
		95% CI	-10.9, -3.0	-9.8, -1.6
		Difference from placebo		
		LS Mean (SE)	-1.2 (2.92)	
		95% CI	-6.9, 4.5	
		p-value	0.6742	
		Corrected Hedges' g (95% CI)	-0.08 (-0.47, 0.31)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	42 (22.8%)
		LS Mean (SE)	-6.2 (2.07)	-7.3 (2.20)
		95% CI	-10.3, -2.2	-11.6, -3.0
		Difference from placebo		
		LS Mean (SE)	1.0 (3.01)	
		95% CI	-4.9, 6.9	
		p-value	0.7376	
		Corrected Hedges' g (95% CI)	0.07 (-0.34, 0.48)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	49 (26.6%)
		LS Mean (SE)	-7.8 (2.07)	-9.0 (2.13)
		95% CI	-11.9, -3.7	-13.2, -4.8
		Difference from placebo		
		LS Mean (SE)	1.2 (2.97)	
		95% CI	-4.6, 7.1	
		p-value	0.6797	
		Corrected Hedges' g (95% CI)	0.08 (-0.31, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	42 (22.8%)
		LS Mean (SE)	-5.5 (2.16)	-8.4 (2.22)
		95% CI	-9.7, -1.2	-12.8, -4.1
		Difference from placebo		
		LS Mean (SE)	3.0 (3.10)	
		95% CI	-3.1, 9.1	
		p-value	0.3349	
		Corrected Hedges' g (95% CI)	0.21 (-0.22, 0.63)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	-5.8 (2.16)	-10.4 (2.23)
		95% CI	-10.0, -1.5	-14.8, -6.0
		Difference from placebo		
		LS Mean (SE)	4.6 (3.10)	
		95% CI	-1.4, 10.7	
		p-value	0.1346	
		Corrected Hedges' g (95% CI)	0.31 (-0.10, 0.73)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	-6.5 (2.18)	-10.1 (2.38)
		95% CI	-10.8, -2.3	-14.7, -5.4
		Difference from placebo		
		LS Mean (SE)	3.5 (3.23)	
		95% CI	-2.8, 9.9	
		p-value	0.2741	
		Corrected Hedges' g (95% CI)	0.24 (-0.20, 0.68)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	-6.0 (2.33)	-7.1 (2.58)
		95% CI	-10.6, -1.4	-12.2, -2.0
		Difference from placebo		
		LS Mean (SE)	1.1 (3.45)	
		95% CI	-5.7, 7.9	
		p-value	0.7515	
		Corrected Hedges' g (95% CI)	0.08 (-0.40, 0.55)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	-8.6 (2.42)	-5.1 (2.82)
		95% CI	-13.4, -3.9	-10.6, 0.4
		Difference from placebo		
		LS Mean (SE)	-3.6 (3.74)	
		95% CI	-10.9, 3.8	
		p-value	0.3416	
		Corrected Hedges' g (95% CI)	-0.25 (-0.77, 0.27)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	-7.8 (2.72)	-8.6 (3.01)
		95% CI	-13.1, -2.5	-14.5, -2.7
		Difference from placebo		
		LS Mean (SE)	0.8 (4.06)	
		95% CI	-7.2, 8.7	
		p-value	0.8453	
		Corrected Hedges' g (95% CI)	0.06 (-0.52, 0.63)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	-7.8 (2.95)	-5.9 (3.32)
		95% CI	-13.6, -2.0	-12.4, 0.6
		Difference from placebo		
		LS Mean (SE)	-1.9 (4.44)	
		95% CI	-10.6, 6.8	
		p-value	0.6726	
		Corrected Hedges' g (95% CI)	-0.14 (-0.78, 0.51)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	-8.1 (3.30)	-3.2 (3.99)
		95% CI	-14.6, -1.7	-11.0, 4.6
		Difference from placebo		
		LS Mean (SE)	-4.9 (5.21)	
		95% CI	-15.1, 5.3	
		p-value	0.3462	
		Corrected Hedges' g (95% CI)	-0.35 (-1.12, 0.41)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	-13.3 (3.92)	-4.6 (4.17)
		95% CI	-21.0, -5.6	-12.8, 3.5
		Difference from placebo		
		LS Mean (SE)	-8.7 (5.71)	
		95% CI	-19.9, 2.5	
		p-value	0.1283	
		Corrected Hedges' g (95% CI)	-0.61 (-1.45, 0.23)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	-16.0 (4.55)	3.7 (6.40)
		95% CI	-24.9, -7.0	-8.8, 16.3
		Difference from placebo		
		LS Mean (SE)	-19.7 (7.84)	
		95% CI	-35.1, -4.3	
		p-value	0.0122	
		Corrected Hedges' g (95% CI)	-1.18 (-2.21, -0.14)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	-15.0 (5.98)	3.3 (12.88)
		95% CI	-26.7, -3.3	-22.0, 28.5
		Difference from placebo		
		LS Mean (SE)	-18.3 (13.69)	
		95% CI	-45.1, 8.6	
		p-value	0.1824	
		Corrected Hedges' g (95% CI)	-1.06 (-2.79, 0.67)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	179 (93.2%)	176 (95.7%)
		LS Mean (SE)	-8.3 (1.46)	-3.7 (1.55)
		95% CI	-11.2, -5.5	-6.7, -0.7
		Difference from placebo		
		LS Mean (SE)	-4.6 (2.13)	
		95% CI	-8.8, -0.4	
		p-value	0.0305	
		Corrected Hedges' g (95% CI)	-0.23 (-0.44, -0.02)	
Week 4	Change from Baseline	n (%)	175 (91.1%)	173 (94.0%)
		LS Mean (SE)	-2.9 (1.88)	1.5 (1.89)
		95% CI	-6.6, 0.8	-2.2, 5.2
		Difference from placebo		
		LS Mean (SE)	-4.4 (2.66)	
		95% CI	-9.6, 0.8	
		p-value	0.0986	
		Corrected Hedges' g (95% CI)	-0.18 (-0.39, 0.03)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	168 (87.5%)	163 (88.6%)
		LS Mean (SE)	-3.7 (1.90)	0.0 (1.91)
		95% CI	-7.4, -0.0	-3.7, 3.8
		Difference from placebo		
		LS Mean (SE)	-3.8 (2.69)	
		95% CI	-9.0, 1.5	
		p-value	0.1618	
		Corrected Hedges' g (95% CI)	-0.15 (-0.37, 0.06)	
Week 10	Change from Baseline	n (%)	163 (84.9%)	156 (84.8%)
		LS Mean (SE)	-6.0 (1.91)	-3.7 (1.94)
		95% CI	-9.7, -2.3	-7.5, 0.1
		Difference from placebo		
		LS Mean (SE)	-2.3 (2.72)	
		95% CI	-7.7, 3.0	
		p-value	0.3940	
		Corrected Hedges' g (95% CI)	-0.10 (-0.31, 0.12)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	154 (80.2%)	149 (81.0%)
		LS Mean (SE)	-7.8 (1.94)	-2.8 (1.96)
		95% CI	-11.6, -4.0	-6.6, 1.1
		Difference from placebo		
		LS Mean (SE)	-5.0 (2.76)	
		95% CI	-10.4, 0.4	
		p-value	0.0687	
		Corrected Hedges' g (95% CI)	-0.21 (-0.43, 0.02)	
Week 16	Change from Baseline	n (%)	150 (78.1%)	149 (81.0%)
		LS Mean (SE)	-14.2 (1.95)	-8.1 (1.97)
		95% CI	-18.0, -10.4	-11.9, -4.2
		Difference from placebo		
		LS Mean (SE)	-6.1 (2.77)	
		95% CI	-11.6, -0.7	
		p-value	0.0270	
		Corrected Hedges' g (95% CI)	-0.26 (-0.48, -0.03)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	151 (78.6%)	150 (81.5%)
		LS Mean (SE)	-14.6 (1.96)	-7.4 (1.97)
		95% CI	-18.5, -10.8	-11.3, -3.5
		Difference from placebo		
		LS Mean (SE)	-7.2 (2.78)	
		95% CI	-12.7, -1.8	
		p-value	0.0093	
		Corrected Hedges' g (95% CI)	-0.30 (-0.53, -0.07)	
Week 25	Change from Baseline	n (%)	136 (70.8%)	133 (72.3%)
		LS Mean (SE)	-10.1 (2.02)	-2.6 (2.04)
		95% CI	-14.0, -6.1	-6.6, 1.3
		Difference from placebo		
		LS Mean (SE)	-7.4 (2.87)	
		95% CI	-13.1, -1.8	
		p-value	0.0096	
		Corrected Hedges' g (95% CI)	-0.32 (-0.56, -0.08)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	124 (64.6%)	131 (71.2%)
		LS Mean (SE)	-4.2 (2.08)	-0.6 (2.07)
		95% CI	-8.3, -0.1	-4.7, 3.4
		Difference from placebo		
		LS Mean (SE)	-3.6 (2.94)	
		95% CI	-9.3, 2.2	
		p-value	0.2218	
		Corrected Hedges' g (95% CI)	-0.15 (-0.40, 0.09)	
Week 37	Change from Baseline	n (%)	113 (58.9%)	107 (58.2%)
		LS Mean (SE)	-5.3 (2.14)	-3.2 (2.19)
		95% CI	-9.5, -1.1	-7.5, 1.1
		Difference from placebo		
		LS Mean (SE)	-2.1 (3.07)	
		95% CI	-8.1, 3.9	
		p-value	0.4872	
		Corrected Hedges' g (95% CI)	-0.09 (-0.36, 0.17)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	103 (53.6%)	106 (57.6%)
		LS Mean (SE)	-4.7 (2.21)	-0.8 (2.23)
		95% CI	-9.0, -0.3	-5.2, 3.6
		Difference from placebo		
		LS Mean (SE)	-3.9 (3.15)	
		95% CI	-10.1, 2.3	
		p-value	0.2166	
		Corrected Hedges' g (95% CI)	-0.17 (-0.44, 0.10)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	83 (45.1%)
		LS Mean (SE)	-4.1 (2.30)	-1.0 (2.38)
		95% CI	-8.6, 0.4	-5.7, 3.7
		Difference from placebo		
		LS Mean (SE)	-3.1 (3.31)	
		95% CI	-9.6, 3.4	
		p-value	0.3483	
		Corrected Hedges' g (95% CI)	-0.14 (-0.44, 0.16)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	89 (46.4%)	83 (45.1%)
		LS Mean (SE)	-6.3 (2.34)	-1.6 (2.41)
		95% CI	-10.9, -1.7	-6.3, 3.2
		Difference from placebo		
		LS Mean (SE)	-4.7 (3.36)	
		95% CI	-11.3, 1.9	
		p-value	0.1617	
		Corrected Hedges' g (95% CI)	-0.21 (-0.51, 0.09)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	65 (35.3%)
		LS Mean (SE)	-6.8 (2.43)	-0.8 (2.59)
		95% CI	-11.5, -2.0	-5.9, 4.3
		Difference from placebo		
		LS Mean (SE)	-6.0 (3.56)	
		95% CI	-12.9, 1.0	
		p-value	0.0937	
		Corrected Hedges' g (95% CI)	-0.28 (-0.61, 0.05)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	72 (39.1%)
		LS Mean (SE)	-5.3 (2.42)	-4.0 (2.55)
		95% CI	-10.0, -0.5	-9.0, 1.0
		Difference from placebo		
		LS Mean (SE)	-1.3 (3.52)	
		95% CI	-8.2, 5.6	
		p-value	0.7140	
		Corrected Hedges' g (95% CI)	-0.06 (-0.38, 0.26)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	62 (33.7%)
		LS Mean (SE)	-5.9 (2.48)	-5.2 (2.67)
		95% CI	-10.8, -1.0	-10.4, 0.0
		Difference from placebo		
		LS Mean (SE)	-0.7 (3.65)	
		95% CI	-7.8, 6.5	
		p-value	0.8528	
		Corrected Hedges' g (95% CI)	-0.03 (-0.37, 0.31)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	65 (33.9%)	57 (31.0%)
		LS Mean (SE)	-5.4 (2.60)	-4.6 (2.76)
		95% CI	-10.4, -0.3	-10.0, 0.8
		Difference from placebo		
		LS Mean (SE)	-0.8 (3.80)	
		95% CI	-8.2, 6.7	
		p-value	0.8345	
		Corrected Hedges' g (95% CI)	-0.04 (-0.39, 0.32)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	-7.7 (2.60)	-2.6 (2.76)
		95% CI	-12.8, -2.6	-8.0, 2.9
		Difference from placebo		
		LS Mean (SE)	-5.2 (3.80)	
		95% CI	-12.6, 2.3	
		p-value	0.1739	
		Corrected Hedges' g (95% CI)	-0.24 (-0.59, 0.11)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	49 (26.6%)
		LS Mean (SE)	-10.4 (2.79)	-5.5 (2.93)
		95% CI	-15.8, -4.9	-11.3, 0.2
		Difference from placebo		
		LS Mean (SE)	-4.9 (4.06)	
		95% CI	-12.8, 3.1	
		p-value	0.2317	
		Corrected Hedges' g (95% CI)	-0.24 (-0.63, 0.15)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	-9.0 (2.68)	-4.4 (2.90)
		95% CI	-14.2, -3.7	-10.1, 1.3
		Difference from placebo		
		LS Mean (SE)	-4.5 (3.96)	
		95% CI	-12.3, 3.2	
		p-value	0.2521	
		Corrected Hedges' g (95% CI)	-0.21 (-0.58, 0.15)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	-6.6 (2.81)	-2.3 (3.07)
		95% CI	-12.1, -1.1	-8.3, 3.7
		Difference from placebo		
		LS Mean (SE)	-4.3 (4.17)	
		95% CI	-12.5, 3.9	
		p-value	0.3004	
		Corrected Hedges' g (95% CI)	-0.21 (-0.61, 0.19)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	-7.0 (2.89)	-3.4 (2.95)
		95% CI	-12.7, -1.3	-9.2, 2.4
		Difference from placebo		
		LS Mean (SE)	-3.6 (4.16)	
		95% CI	-11.8, 4.5	
		p-value	0.3845	
		Corrected Hedges' g (95% CI)	-0.17 (-0.56, 0.22)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	42 (22.8%)
		LS Mean (SE)	-9.1 (2.93)	-5.0 (3.11)
		95% CI	-14.9, -3.4	-11.1, 1.1
		Difference from placebo		
		LS Mean (SE)	-4.1 (4.29)	
		95% CI	-12.5, 4.3	
		p-value	0.3391	
		Corrected Hedges' g (95% CI)	-0.20 (-0.61, 0.21)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	50 (27.2%)
		LS Mean (SE)	-5.8 (2.92)	-10.6 (2.97)
		95% CI	-11.5, -0.1	-16.4, -4.8
		Difference from placebo		
		LS Mean (SE)	4.8 (4.17)	
		95% CI	-3.4, 13.0	
		p-value	0.2480	
		Corrected Hedges' g (95% CI)	0.23 (-0.16, 0.62)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	43 (23.4%)
		LS Mean (SE)	-7.3 (3.07)	-5.6 (3.11)
		95% CI	-13.3, -1.3	-11.7, 0.5
		Difference from placebo		
		LS Mean (SE)	-1.7 (4.39)	
		95% CI	-10.3, 6.9	
		p-value	0.7043	
		Corrected Hedges' g (95% CI)	-0.08 (-0.50, 0.34)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	-7.9 (3.03)	-9.8 (3.14)
		95% CI	-13.9, -2.0	-15.9, -3.6
		Difference from placebo		
		LS Mean (SE)	1.9 (4.37)	
		95% CI	-6.7, 10.4	
		p-value	0.6702	
		Corrected Hedges' g (95% CI)	0.09 (-0.33, 0.51)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	-6.1 (3.08)	-7.2 (3.38)
		95% CI	-12.1, -0.1	-13.8, -0.5
		Difference from placebo		
		LS Mean (SE)	1.1 (4.60)	
		95% CI	-8.0, 10.1	
		p-value	0.8169	
		Corrected Hedges' g (95% CI)	0.05 (-0.39, 0.49)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	-8.2 (3.29)	-8.1 (3.67)
		95% CI	-14.6, -1.7	-15.3, -0.9
		Difference from placebo		
		LS Mean (SE)	-0.0 (4.97)	
		95% CI	-9.8, 9.7	
		p-value	0.9935	
		Corrected Hedges' g (95% CI)	-0.00 (-0.48, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	-7.9 (3.46)	-4.4 (4.05)
		95% CI	-14.6, -1.1	-12.3, 3.6
		Difference from placebo		
		LS Mean (SE)	-3.5 (5.42)	
		95% CI	-14.1, 7.1	
		p-value	0.5188	
		Corrected Hedges' g (95% CI)	-0.17 (-0.69, 0.35)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	-10.5 (3.84)	-3.5 (4.28)
		95% CI	-18.1, -3.0	-11.9, 4.9
		Difference from placebo		
		LS Mean (SE)	-7.0 (5.74)	
		95% CI	-18.2, 4.3	
		p-value	0.2229	
		Corrected Hedges' g (95% CI)	-0.35 (-0.93, 0.23)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	-13.5 (4.24)	2.7 (4.76)
		95% CI	-21.8, -5.2	-6.6, 12.1
		Difference from placebo		
		LS Mean (SE)	-16.2 (6.41)	
		95% CI	-28.8, -3.6	
		p-value	0.0116	
		Corrected Hedges' g (95% CI)	-0.81 (-1.48, -0.15)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	-10.6 (4.83)	1.5 (5.82)
		95% CI	-20.0, -1.1	-10.0, 12.9
		Difference from placebo		
		LS Mean (SE)	-12.0 (7.79)	
		95% CI	-27.3, 3.3	
		p-value	0.1229	
		Corrected Hedges' g (95% CI)	-0.59 (-1.37, 0.18)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	-14.0 (5.60)	-5.2 (5.83)
		95% CI	-25.0, -3.1	-16.7, 6.2
		Difference from placebo		
		LS Mean (SE)	-8.8 (8.10)	
		95% CI	-24.7, 7.1	
		p-value	0.2774	
		Corrected Hedges' g (95% CI)	-0.44 (-1.27, 0.39)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	-18.6 (6.79)	0.1 (7.57)
		95% CI	-31.9, -5.2	-14.7, 14.9
		Difference from placebo		
		LS Mean (SE)	-18.7 (10.86)	
		95% CI	-40.0, 2.6	
		p-value	0.0857	
		Corrected Hedges' g (95% CI)	-0.85 (-1.84, 0.15)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	-16.0 (8.81)	-7.9 (13.13)
		95% CI	-33.3, 1.3	-33.6, 17.9
		Difference from placebo		
		LS Mean (SE)	-8.1 (16.11)	
		95% CI	-39.7, 23.5	
		p-value	0.6137	
		Corrected Hedges' g (95% CI)	-0.35 (-2.00, 1.30)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	176 (95.7%)
		LS Mean (SE)	1.7 (0.99)	2.9 (1.05)
		95% CI	-0.2, 3.7	0.8, 4.9
		Difference from placebo		
		LS Mean (SE)	-1.2 (1.45)	
		95% CI	-4.0, 1.7	
		p-value	0.4275	
		Corrected Hedges' g (95% CI)	-0.08 (-0.29, 0.12)	
Week 4	Change from Baseline	n (%)	177 (92.2%)	174 (94.6%)
		LS Mean (SE)	3.9 (1.28)	3.4 (1.29)
		95% CI	1.4, 6.4	0.9, 5.9
		Difference from placebo		
		LS Mean (SE)	0.5 (1.82)	
		95% CI	-3.1, 4.1	
		p-value	0.7827	
		Corrected Hedges' g (95% CI)	0.03 (-0.18, 0.24)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	169 (88.0%)	165 (89.7%)
		LS Mean (SE)	2.4 (1.29)	2.6 (1.31)
		95% CI	-0.1, 5.0	0.1, 5.2
		Difference from placebo		
		LS Mean (SE)	-0.2 (1.84)	
		95% CI	-3.8, 3.4	
		p-value	0.9085	
		Corrected Hedges' g (95% CI)	-0.01 (-0.23, 0.20)	
Week 10	Change from Baseline	n (%)	165 (85.9%)	156 (84.8%)
		LS Mean (SE)	2.2 (1.30)	4.4 (1.33)
		95% CI	-0.4, 4.7	1.8, 7.0
		Difference from placebo		
		LS Mean (SE)	-2.2 (1.86)	
		95% CI	-5.8, 1.5	
		p-value	0.2395	
		Corrected Hedges' g (95% CI)	-0.13 (-0.35, 0.09)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	149 (81.0%)
		LS Mean (SE)	1.4 (1.31)	1.9 (1.35)
		95% CI	-1.1, 4.0	-0.8, 4.5
		Difference from placebo		
		LS Mean (SE)	-0.4 (1.89)	
		95% CI	-4.1, 3.3	
		p-value	0.8156	
		Corrected Hedges' g (95% CI)	-0.03 (-0.25, 0.20)	
Week 16	Change from Baseline	n (%)	151 (78.6%)	148 (80.4%)
		LS Mean (SE)	-0.4 (1.33)	1.4 (1.35)
		95% CI	-3.0, 2.2	-1.3, 4.0
		Difference from placebo		
		LS Mean (SE)	-1.8 (1.90)	
		95% CI	-5.5, 2.0	
		p-value	0.3519	
		Corrected Hedges' g (95% CI)	-0.11 (-0.33, 0.12)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	150 (81.5%)
		LS Mean (SE)	-0.7 (1.33)	2.1 (1.35)
		95% CI	-3.3, 1.9	-0.5, 4.8
		Difference from placebo		
		LS Mean (SE)	-2.8 (1.90)	
		95% CI	-6.5, 0.9	
		p-value	0.1376	
		Corrected Hedges' g (95% CI)	-0.17 (-0.40, 0.06)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	133 (72.3%)
		LS Mean (SE)	0.5 (1.37)	0.6 (1.40)
		95% CI	-2.2, 3.2	-2.1, 3.4
		Difference from placebo		
		LS Mean (SE)	-0.1 (1.96)	
		95% CI	-4.0, 3.7	
		p-value	0.9565	
		Corrected Hedges' g (95% CI)	-0.01 (-0.24, 0.23)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	127 (66.1%)	132 (71.7%)
		LS Mean (SE)	1.5 (1.41)	3.4 (1.41)
		95% CI	-1.2, 4.3	0.6, 6.2
		Difference from placebo		
		LS Mean (SE)	-1.9 (2.00)	
		95% CI	-5.8, 2.0	
		p-value	0.3462	
		Corrected Hedges' g (95% CI)	-0.12 (-0.36, 0.13)	
Week 37	Change from Baseline	n (%)	113 (58.9%)	106 (57.6%)
		LS Mean (SE)	3.0 (1.47)	3.5 (1.51)
		95% CI	0.1, 5.9	0.5, 6.4
		Difference from placebo		
		LS Mean (SE)	-0.5 (2.10)	
		95% CI	-4.6, 3.6	
		p-value	0.8211	
		Corrected Hedges' g (95% CI)	-0.03 (-0.30, 0.23)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	105 (54.7%)	106 (57.6%)
		LS Mean (SE)	2.8 (1.51)	3.4 (1.52)
		95% CI	-0.2, 5.7	0.4, 6.3
		Difference from placebo		
		LS Mean (SE)	-0.6 (2.15)	
		95% CI	-4.8, 3.6	
		p-value	0.7874	
		Corrected Hedges' g (95% CI)	-0.04 (-0.31, 0.23)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	83 (45.1%)
		LS Mean (SE)	0.9 (1.57)	5.5 (1.64)
		95% CI	-2.2, 4.0	2.3, 8.7
		Difference from placebo		
		LS Mean (SE)	-4.6 (2.28)	
		95% CI	-9.1, -0.1	
		p-value	0.0438	
		Corrected Hedges' g (95% CI)	-0.30 (-0.60, -0.01)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	90 (46.9%)	83 (45.1%)
		LS Mean (SE)	0.9 (1.59)	0.2 (1.65)
		95% CI	-2.2, 4.0	-3.0, 3.5
		Difference from placebo		
		LS Mean (SE)	0.7 (2.30)	
		95% CI	-3.8, 5.2	
		p-value	0.7748	
		Corrected Hedges' g (95% CI)	0.04 (-0.25, 0.34)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	65 (35.3%)
		LS Mean (SE)	1.6 (1.67)	2.2 (1.79)
		95% CI	-1.7, 4.9	-1.3, 5.7
		Difference from placebo		
		LS Mean (SE)	-0.6 (2.45)	
		95% CI	-5.4, 4.2	
		p-value	0.8156	
		Corrected Hedges' g (95% CI)	-0.04 (-0.37, 0.29)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	72 (39.1%)
		LS Mean (SE)	0.3 (1.66)	0.7 (1.74)
		95% CI	-2.9, 3.6	-2.7, 4.1
		Difference from placebo		
		LS Mean (SE)	-0.4 (2.41)	
		95% CI	-5.1, 4.3	
		p-value	0.8630	
		Corrected Hedges' g (95% CI)	-0.03 (-0.35, 0.29)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	62 (33.7%)
		LS Mean (SE)	1.2 (1.70)	2.3 (1.83)
		95% CI	-2.1, 4.5	-1.3, 5.8
		Difference from placebo		
		LS Mean (SE)	-1.1 (2.50)	
		95% CI	-6.0, 3.8	
		p-value	0.6713	
		Corrected Hedges' g (95% CI)	-0.07 (-0.41, 0.26)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	65 (33.9%)	57 (31.0%)
		LS Mean (SE)	2.1 (1.79)	2.5 (1.89)
		95% CI	-1.5, 5.6	-1.2, 6.2
		Difference from placebo		
		LS Mean (SE)	-0.5 (2.61)	
		95% CI	-5.6, 4.7	
		p-value	0.8579	
		Corrected Hedges' g (95% CI)	-0.03 (-0.39, 0.32)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	57 (31.0%)
		LS Mean (SE)	-0.8 (1.78)	3.7 (1.90)
		95% CI	-4.3, 2.7	-0.1, 7.4
		Difference from placebo		
		LS Mean (SE)	-4.5 (2.60)	
		95% CI	-9.6, 0.6	
		p-value	0.0854	
		Corrected Hedges' g (95% CI)	-0.31 (-0.66, 0.05)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	49 (26.6%)
		LS Mean (SE)	0.2 (1.92)	2.4 (2.00)
		95% CI	-3.5, 4.0	-1.6, 6.3
		Difference from placebo		
		LS Mean (SE)	-2.1 (2.78)	
		95% CI	-7.6, 3.3	
		p-value	0.4460	
		Corrected Hedges' g (95% CI)	-0.15 (-0.54, 0.24)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	1.3 (1.84)	4.1 (1.98)
		95% CI	-2.3, 4.9	0.2, 7.9
		Difference from placebo		
		LS Mean (SE)	-2.7 (2.71)	
		95% CI	-8.1, 2.6	
		p-value	0.3103	
		Corrected Hedges' g (95% CI)	-0.19 (-0.56, 0.18)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	1.3 (1.93)	2.8 (2.12)
		95% CI	-2.4, 5.1	-1.4, 7.0
		Difference from placebo		
		LS Mean (SE)	-1.5 (2.88)	
		95% CI	-7.1, 4.2	
		p-value	0.6092	
		Corrected Hedges' g (95% CI)	-0.10 (-0.50, 0.30)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	0.2 (1.97)	0.3 (2.00)
		95% CI	-3.6, 4.1	-3.7, 4.2
		Difference from placebo		
		LS Mean (SE)	-0.0 (2.81)	
		95% CI	-5.5, 5.5	
		p-value	0.9898	
		Corrected Hedges' g (95% CI)	-0.00 (-0.39, 0.39)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	42 (22.8%)
		LS Mean (SE)	1.6 (2.01)	0.3 (2.13)
		95% CI	-2.3, 5.6	-3.9, 4.5
		Difference from placebo		
		LS Mean (SE)	1.3 (2.93)	
		95% CI	-4.4, 7.1	
		p-value	0.6529	
		Corrected Hedges' g (95% CI)	0.09 (-0.32, 0.51)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	50 (27.2%)
		LS Mean (SE)	1.2 (1.99)	0.5 (2.02)
		95% CI	-2.7, 5.1	-3.4, 4.5
		Difference from placebo		
		LS Mean (SE)	0.7 (2.84)	
		95% CI	-4.9, 6.2	
		p-value	0.8141	
		Corrected Hedges' g (95% CI)	0.05 (-0.35, 0.44)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	43 (23.4%)
		LS Mean (SE)	1.6 (2.11)	0.9 (2.12)
		95% CI	-2.5, 5.8	-3.3, 5.1
		Difference from placebo		
		LS Mean (SE)	0.8 (3.01)	
		95% CI	-5.1, 6.6	
		p-value	0.8024	
		Corrected Hedges' g (95% CI)	0.05 (-0.37, 0.47)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	3.1 (2.07)	3.4 (2.14)
		95% CI	-0.9, 7.2	-0.8, 7.6
		Difference from placebo		
		LS Mean (SE)	-0.3 (2.98)	
		95% CI	-6.1, 5.6	
		p-value	0.9287	
		Corrected Hedges' g (95% CI)	-0.02 (-0.43, 0.40)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	4.2 (2.10)	-0.1 (2.29)
		95% CI	0.0, 8.3	-4.6, 4.4
		Difference from placebo		
		LS Mean (SE)	4.2 (3.11)	
		95% CI	-1.9, 10.3	
		p-value	0.1729	
		Corrected Hedges' g (95% CI)	0.30 (-0.14, 0.74)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	3.3 (2.25)	2.2 (2.46)
		95% CI	-1.1, 7.7	-2.6, 7.0
		Difference from placebo		
		LS Mean (SE)	1.1 (3.34)	
		95% CI	-5.4, 7.6	
		p-value	0.7412	
		Corrected Hedges' g (95% CI)	0.08 (-0.40, 0.56)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	3.4 (2.36)	4.3 (2.72)
		95% CI	-1.2, 8.0	-1.0, 9.6
		Difference from placebo		
		LS Mean (SE)	-0.9 (3.61)	
		95% CI	-8.0, 6.2	
		p-value	0.8096	
		Corrected Hedges' g (95% CI)	-0.06 (-0.58, 0.46)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	0.9 (2.62)	5.1 (2.91)
		95% CI	-4.3, 6.0	-0.6, 10.8
		Difference from placebo		
		LS Mean (SE)	-4.3 (3.92)	
		95% CI	-12.0, 3.4	
		p-value	0.2741	
		Corrected Hedges' g (95% CI)	-0.32 (-0.89, 0.26)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	0.6 (2.95)	4.8 (3.22)
		95% CI	-5.2, 6.4	-1.5, 11.1
		Difference from placebo		
		LS Mean (SE)	-4.2 (4.40)	
		95% CI	-12.8, 4.5	
		p-value	0.3430	
		Corrected Hedges' g (95% CI)	-0.30 (-0.95, 0.34)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	4.2 (3.28)	3.5 (3.90)
		95% CI	-2.2, 10.6	-4.1, 11.2
		Difference from placebo		
		LS Mean (SE)	0.7 (5.15)	
		95% CI	-9.4, 10.8	
		p-value	0.8957	
		Corrected Hedges' g (95% CI)	0.05 (-0.71, 0.81)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	7.2 (3.83)	2.8 (3.96)
		95% CI	-0.3, 14.7	-4.9, 10.6
		Difference from placebo		
		LS Mean (SE)	4.3 (5.54)	
		95% CI	-6.5, 15.2	
		p-value	0.4337	
		Corrected Hedges' g (95% CI)	0.32 (-0.51, 1.14)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	3.5 (4.40)	4.5 (4.61)
		95% CI	-5.1, 12.1	-4.5, 13.6
		Difference from placebo		
		LS Mean (SE)	-1.0 (6.35)	
		95% CI	-13.5, 11.4	
		p-value	0.8720	
		Corrected Hedges' g (95% CI)	-0.07 (-1.03, 0.88)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	-2.5 (6.07)	11.9 (9.10)
		95% CI	-14.4, 9.3	-6.0, 29.7
		Difference from placebo		
		LS Mean (SE)	-14.4 (11.23)	
		95% CI	-36.4, 7.6	
		p-value	0.1993	
		Corrected Hedges' g (95% CI)	-0.90 (-2.61, 0.80)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	176 (95.7%)
		LS Mean (SE)	-7.1 (1.04)	-4.8 (1.12)
		95% CI	-9.2, -5.1	-7.0, -2.6
		Difference from placebo		
		LS Mean (SE)	-2.4 (1.54)	
		95% CI	-5.4, 0.6	
		p-value	0.1234	
		Corrected Hedges' g (95% CI)	-0.16 (-0.37, 0.04)	
Week 4	Change from Baseline	n (%)	177 (92.2%)	174 (94.6%)
		LS Mean (SE)	-3.5 (1.33)	-1.4 (1.35)
		95% CI	-6.1, -0.9	-4.0, 1.3
		Difference from placebo		
		LS Mean (SE)	-2.1 (1.90)	
		95% CI	-5.8, 1.6	
		p-value	0.2689	
		Corrected Hedges' g (95% CI)	-0.12 (-0.33, 0.09)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	169 (88.0%)	165 (89.7%)
		LS Mean (SE)	-5.8 (1.35)	-2.7 (1.37)
		95% CI	-8.5, -3.2	-5.4, 0.0
		Difference from placebo		
		LS Mean (SE)	-3.1 (1.92)	
		95% CI	-6.9, 0.6	
		p-value	0.1019	
		Corrected Hedges' g (95% CI)	-0.18 (-0.39, 0.04)	
Week 10	Change from Baseline	n (%)	166 (86.5%)	156 (84.8%)
		LS Mean (SE)	-5.8 (1.35)	-4.4 (1.39)
		95% CI	-8.4, -3.1	-7.1, -1.6
		Difference from placebo		
		LS Mean (SE)	-1.4 (1.94)	
		95% CI	-5.2, 2.4	
		p-value	0.4737	
		Corrected Hedges' g (95% CI)	-0.08 (-0.30, 0.14)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	149 (81.0%)
		LS Mean (SE)	-6.9 (1.38)	-5.2 (1.41)
		95% CI	-9.6, -4.2	-8.0, -2.4
		Difference from placebo		
		LS Mean (SE)	-1.7 (1.97)	
		95% CI	-5.5, 2.2	
		p-value	0.3922	
		Corrected Hedges' g (95% CI)	-0.10 (-0.32, 0.13)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	148 (80.4%)
		LS Mean (SE)	-8.4 (1.39)	-7.3 (1.41)
		95% CI	-11.1, -5.7	-10.1, -4.5
		Difference from placebo		
		LS Mean (SE)	-1.1 (1.98)	
		95% CI	-5.0, 2.8	
		p-value	0.5830	
		Corrected Hedges' g (95% CI)	-0.06 (-0.29, 0.16)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	150 (81.5%)
		LS Mean (SE)	-8.0 (1.39)	-6.8 (1.41)
		95% CI	-10.8, -5.3	-9.6, -4.1
		Difference from placebo		
		LS Mean (SE)	-1.2 (1.98)	
		95% CI	-5.1, 2.7	
		p-value	0.5411	
		Corrected Hedges' g (95% CI)	-0.07 (-0.30, 0.16)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	133 (72.3%)
		LS Mean (SE)	-7.1 (1.44)	-7.0 (1.46)
		95% CI	-10.0, -4.3	-9.8, -4.1
		Difference from placebo		
		LS Mean (SE)	-0.2 (2.05)	
		95% CI	-4.2, 3.8	
		p-value	0.9286	
		Corrected Hedges' g (95% CI)	-0.01 (-0.25, 0.23)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	127 (66.1%)	132 (71.7%)
		LS Mean (SE)	-5.8 (1.48)	-8.1 (1.47)
		95% CI	-8.7, -2.9	-11.0, -5.2
		Difference from placebo		
		LS Mean (SE)	2.3 (2.09)	
		95% CI	-1.8, 6.4	
		p-value	0.2684	
		Corrected Hedges' g (95% CI)	0.14 (-0.11, 0.38)	
Week 37	Change from Baseline	n (%)	113 (58.9%)	106 (57.6%)
		LS Mean (SE)	-4.8 (1.53)	-5.3 (1.58)
		95% CI	-7.8, -1.8	-8.4, -2.2
		Difference from placebo		
		LS Mean (SE)	0.6 (2.20)	
		95% CI	-3.8, 4.9	
		p-value	0.8021	
		Corrected Hedges' g (95% CI)	0.03 (-0.23, 0.30)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	105 (54.7%)	106 (57.6%)
		LS Mean (SE)	-4.6 (1.57)	-4.6 (1.59)
		95% CI	-7.7, -1.5	-7.7, -1.5
		Difference from placebo		
		LS Mean (SE)	0.0 (2.24)	
		95% CI	-4.4, 4.4	
		p-value	0.9961	
		Corrected Hedges' g (95% CI)	0.00 (-0.27, 0.27)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	83 (45.1%)
		LS Mean (SE)	-6.9 (1.64)	-4.3 (1.71)
		95% CI	-10.1, -3.7	-7.6, -0.9
		Difference from placebo		
		LS Mean (SE)	-2.6 (2.37)	
		95% CI	-7.3, 2.0	
		p-value	0.2709	
		Corrected Hedges' g (95% CI)	-0.17 (-0.46, 0.13)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	90 (46.9%)	83 (45.1%)
		LS Mean (SE)	-6.2 (1.66)	-6.3 (1.73)
		95% CI	-9.5, -3.0	-9.7, -2.9
		Difference from placebo		
		LS Mean (SE)	0.1 (2.40)	
		95% CI	-4.6, 4.8	
		p-value	0.9788	
		Corrected Hedges' g (95% CI)	0.00 (-0.29, 0.30)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	65 (35.3%)
		LS Mean (SE)	-7.0 (1.74)	-5.7 (1.86)
		95% CI	-10.4, -3.6	-9.3, -2.0
		Difference from placebo		
		LS Mean (SE)	-1.3 (2.55)	
		95% CI	-6.3, 3.7	
		p-value	0.5984	
		Corrected Hedges' g (95% CI)	-0.09 (-0.42, 0.24)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	72 (39.1%)
		LS Mean (SE)	-8.5 (1.73)	-4.9 (1.82)
		95% CI	-11.9, -5.1	-8.5, -1.3
		Difference from placebo		
		LS Mean (SE)	-3.6 (2.51)	
		95% CI	-8.5, 1.3	
		p-value	0.1537	
		Corrected Hedges' g (95% CI)	-0.23 (-0.55, 0.09)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	62 (33.7%)
		LS Mean (SE)	-7.2 (1.78)	-4.9 (1.91)
		95% CI	-10.7, -3.7	-8.6, -1.1
		Difference from placebo		
		LS Mean (SE)	-2.3 (2.61)	
		95% CI	-7.4, 2.8	
		p-value	0.3789	
		Corrected Hedges' g (95% CI)	-0.15 (-0.49, 0.19)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	65 (33.9%)	57 (31.0%)
		LS Mean (SE)	-6.4 (1.86)	-4.2 (1.97)
		95% CI	-10.0, -2.7	-8.1, -0.3
		Difference from placebo		
		LS Mean (SE)	-2.2 (2.72)	
		95% CI	-7.5, 3.2	
		p-value	0.4243	
		Corrected Hedges' g (95% CI)	-0.14 (-0.50, 0.21)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	-8.1 (1.85)	-4.6 (1.97)
		95% CI	-11.7, -4.5	-8.4, -0.7
		Difference from placebo		
		LS Mean (SE)	-3.5 (2.70)	
		95% CI	-8.8, 1.8	
		p-value	0.1923	
		Corrected Hedges' g (95% CI)	-0.23 (-0.58, 0.12)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	49 (26.6%)
		LS Mean (SE)	-9.4 (2.01)	-4.5 (2.09)
		95% CI	-13.3, -5.5	-8.6, -0.4
		Difference from placebo		
		LS Mean (SE)	-4.9 (2.90)	
		95% CI	-10.6, 0.8	
		p-value	0.0929	
		Corrected Hedges' g (95% CI)	-0.33 (-0.72, 0.06)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	-7.2 (1.90)	-3.7 (2.06)
		95% CI	-10.9, -3.5	-7.7, 0.4
		Difference from placebo		
		LS Mean (SE)	-3.5 (2.81)	
		95% CI	-9.0, 2.0	
		p-value	0.2102	
		Corrected Hedges' g (95% CI)	-0.23 (-0.60, 0.14)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	-5.6 (2.01)	-5.1 (2.20)
		95% CI	-9.5, -1.7	-9.4, -0.8
		Difference from placebo		
		LS Mean (SE)	-0.5 (2.98)	
		95% CI	-6.4, 5.3	
		p-value	0.8617	
		Corrected Hedges' g (95% CI)	-0.04 (-0.44, 0.37)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	-9.4 (2.06)	-5.9 (2.09)
		95% CI	-13.4, -5.4	-10.0, -1.8
		Difference from placebo		
		LS Mean (SE)	-3.5 (2.95)	
		95% CI	-9.3, 2.3	
		p-value	0.2325	
		Corrected Hedges' g (95% CI)	-0.24 (-0.63, 0.15)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	42 (22.8%)
		LS Mean (SE)	-8.1 (2.09)	-7.1 (2.22)
		95% CI	-12.2, -4.0	-11.5, -2.8
		Difference from placebo		
		LS Mean (SE)	-0.9 (3.05)	
		95% CI	-6.9, 5.0	
		p-value	0.7556	
		Corrected Hedges' g (95% CI)	-0.06 (-0.48, 0.35)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	50 (27.2%)
		LS Mean (SE)	-6.9 (2.09)	-9.6 (2.10)
		95% CI	-11.0, -2.8	-13.8, -5.5
		Difference from placebo		
		LS Mean (SE)	2.7 (2.97)	
		95% CI	-3.1, 8.6	
		p-value	0.3557	
		Corrected Hedges' g (95% CI)	0.18 (-0.21, 0.58)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	43 (23.4%)
		LS Mean (SE)	-7.2 (2.18)	-7.1 (2.22)
		95% CI	-11.4, -2.9	-11.4, -2.7
		Difference from placebo		
		LS Mean (SE)	-0.1 (3.12)	
		95% CI	-6.2, 6.0	
		p-value	0.9778	
		Corrected Hedges' g (95% CI)	-0.01 (-0.43, 0.41)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	-5.7 (2.17)	-5.9 (2.23)
		95% CI	-10.0, -1.5	-10.3, -1.5
		Difference from placebo		
		LS Mean (SE)	0.2 (3.13)	
		95% CI	-5.9, 6.3	
		p-value	0.9501	
		Corrected Hedges' g (95% CI)	0.01 (-0.40, 0.43)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	-4.2 (2.18)	-6.3 (2.39)
		95% CI	-8.5, 0.1	-11.0, -1.7
		Difference from placebo		
		LS Mean (SE)	2.1 (3.24)	
		95% CI	-4.2, 8.5	
		p-value	0.5076	
		Corrected Hedges' g (95% CI)	0.15 (-0.29, 0.59)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	-7.9 (2.36)	-5.6 (2.58)
		95% CI	-12.5, -3.2	-10.6, -0.5
		Difference from placebo		
		LS Mean (SE)	-2.3 (3.52)	
		95% CI	-9.2, 4.6	
		p-value	0.5155	
		Corrected Hedges' g (95% CI)	-0.16 (-0.64, 0.32)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	-7.9 (2.46)	-2.7 (2.85)
		95% CI	-12.7, -3.0	-8.3, 2.9
		Difference from placebo		
		LS Mean (SE)	-5.1 (3.79)	
		95% CI	-12.6, 2.3	
		p-value	0.1761	
		Corrected Hedges' g (95% CI)	-0.35 (-0.88, 0.17)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	-8.3 (2.74)	-7.2 (3.05)
		95% CI	-13.7, -2.9	-13.1, -1.2
		Difference from placebo		
		LS Mean (SE)	-1.2 (4.09)	
		95% CI	-9.2, 6.9	
		p-value	0.7785	
		Corrected Hedges' g (95% CI)	-0.08 (-0.66, 0.49)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	-7.9 (3.05)	-5.4 (3.37)
		95% CI	-13.9, -1.9	-12.0, 1.2
		Difference from placebo		
		LS Mean (SE)	-2.5 (4.59)	
		95% CI	-11.5, 6.5	
		p-value	0.5841	
		Corrected Hedges' g (95% CI)	-0.18 (-0.82, 0.46)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	-6.3 (3.44)	-2.3 (4.07)
		95% CI	-13.0, 0.4	-10.3, 5.6
		Difference from placebo		
		LS Mean (SE)	-4.0 (5.41)	
		95% CI	-14.6, 6.6	
		p-value	0.4636	
		Corrected Hedges' g (95% CI)	-0.28 (-1.04, 0.49)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	-7.1 (3.98)	-0.4 (4.78)
		95% CI	-14.9, 0.7	-9.7, 9.0
		Difference from placebo		
		LS Mean (SE)	-6.7 (6.10)	
		95% CI	-18.7, 5.2	
		p-value	0.2684	
		Corrected Hedges' g (95% CI)	-0.44 (-1.27, 0.39)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	-17.3 (4.82)	8.2 (6.24)
		95% CI	-26.8, -7.9	-4.0, 20.4
		Difference from placebo		
		LS Mean (SE)	-25.5 (8.64)	
		95% CI	-42.5, -8.6	
		p-value	0.0031	
		Corrected Hedges' g (95% CI)	-1.51 (-2.59, -0.43)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	-5.3 (6.70)	-3.7 (9.92)
		95% CI	-18.4, 7.8	-23.2, 15.7
		Difference from placebo		
		LS Mean (SE)	-1.6 (12.76)	
		95% CI	-26.6, 23.4	
		p-value	0.9018	
		Corrected Hedges' g (95% CI)	-0.09 (-1.73, 1.55)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	175 (95.1%)
		LS Mean (SE)	-5.4 (1.32)	-1.8 (1.38)
		95% CI	-8.0, -2.8	-4.5, 1.0
		Difference from placebo		
		LS Mean (SE)	-3.6 (1.91)	
		95% CI	-7.4, 0.1	
		p-value	0.0583	
		Corrected Hedges' g (95% CI)	-0.20 (-0.41, 0.01)	
Week 4	Change from Baseline	n (%)	177 (92.2%)	173 (94.0%)
		LS Mean (SE)	-4.2 (1.71)	-2.1 (1.73)
		95% CI	-7.5, -0.8	-5.5, 1.3
		Difference from placebo		
		LS Mean (SE)	-2.1 (2.43)	
		95% CI	-6.9, 2.7	
		p-value	0.3878	
		Corrected Hedges' g (95% CI)	-0.09 (-0.30, 0.12)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	169 (88.0%)	164 (89.1%)
		LS Mean (SE)	-4.6 (1.72)	-1.5 (1.75)
		95% CI	-7.9, -1.2	-4.9, 1.9
		Difference from placebo		
		LS Mean (SE)	-3.0 (2.45)	
		95% CI	-7.9, 1.8	
		p-value	0.2160	
		Corrected Hedges' g (95% CI)	-0.14 (-0.35, 0.08)	
Week 10	Change from Baseline	n (%)	165 (85.9%)	155 (84.2%)
		LS Mean (SE)	-4.9 (1.73)	-3.0 (1.77)
		95% CI	-8.3, -1.5	-6.5, 0.4
		Difference from placebo		
		LS Mean (SE)	-1.9 (2.48)	
		95% CI	-6.7, 3.0	
		p-value	0.4530	
		Corrected Hedges' g (95% CI)	-0.08 (-0.30, 0.14)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	148 (80.4%)
		LS Mean (SE)	-6.2 (1.75)	-5.0 (1.80)
		95% CI	-9.6, -2.7	-8.5, -1.5
		Difference from placebo		
		LS Mean (SE)	-1.2 (2.51)	
		95% CI	-6.1, 3.7	
		p-value	0.6346	
		Corrected Hedges' g (95% CI)	-0.05 (-0.28, 0.17)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	147 (79.9%)
		LS Mean (SE)	-8.2 (1.77)	-4.8 (1.80)
		95% CI	-11.7, -4.8	-8.3, -1.2
		Difference from placebo		
		LS Mean (SE)	-3.5 (2.53)	
		95% CI	-8.5, 1.5	
		p-value	0.1672	
		Corrected Hedges' g (95% CI)	-0.16 (-0.39, 0.07)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	149 (81.0%)
		LS Mean (SE)	-7.6 (1.78)	-4.1 (1.81)
		95% CI	-11.1, -4.1	-7.6, -0.6
		Difference from placebo		
		LS Mean (SE)	-3.5 (2.54)	
		95% CI	-8.4, 1.5	
		p-value	0.1709	
		Corrected Hedges' g (95% CI)	-0.16 (-0.38, 0.07)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	132 (71.7%)
		LS Mean (SE)	-6.5 (1.83)	-0.8 (1.87)
		95% CI	-10.1, -2.9	-4.5, 2.8
		Difference from placebo		
		LS Mean (SE)	-5.7 (2.61)	
		95% CI	-10.8, -0.6	
		p-value	0.0298	
		Corrected Hedges' g (95% CI)	-0.26 (-0.50, -0.02)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	127 (66.1%)	131 (71.2%)
		LS Mean (SE)	-4.1 (1.88)	-2.0 (1.89)
		95% CI	-7.8, -0.4	-5.8, 1.7
		Difference from placebo		
		LS Mean (SE)	-2.0 (2.67)	
		95% CI	-7.3, 3.2	
		p-value	0.4492	
		Corrected Hedges' g (95% CI)	-0.09 (-0.34, 0.15)	
Week 37	Change from Baseline	n (%)	113 (58.9%)	105 (57.1%)
		LS Mean (SE)	-2.4 (1.95)	-1.3 (2.01)
		95% CI	-6.2, 1.5	-5.2, 2.7
		Difference from placebo		
		LS Mean (SE)	-1.1 (2.81)	
		95% CI	-6.6, 4.4	
		p-value	0.6992	
		Corrected Hedges' g (95% CI)	-0.05 (-0.32, 0.21)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	105 (54.7%)	105 (57.1%)
		LS Mean (SE)	-3.7 (2.00)	-0.8 (2.04)
		95% CI	-7.6, 0.2	-4.7, 3.2
		Difference from placebo		
		LS Mean (SE)	-2.9 (2.86)	
		95% CI	-8.5, 2.7	
		p-value	0.3058	
		Corrected Hedges' g (95% CI)	-0.14 (-0.41, 0.13)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	82 (44.6%)
		LS Mean (SE)	-3.0 (2.09)	-0.8 (2.18)
		95% CI	-7.1, 1.1	-5.1, 3.4
		Difference from placebo		
		LS Mean (SE)	-2.1 (3.03)	
		95% CI	-8.1, 3.8	
		p-value	0.4804	
		Corrected Hedges' g (95% CI)	-0.11 (-0.40, 0.19)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	89 (46.4%)	82 (44.6%)
		LS Mean (SE)	-4.0 (2.13)	-3.6 (2.20)
		95% CI	-8.1, 0.2	-7.9, 0.7
		Difference from placebo		
		LS Mean (SE)	-0.4 (3.06)	
		95% CI	-6.4, 5.6	
		p-value	0.8994	
		Corrected Hedges' g (95% CI)	-0.02 (-0.32, 0.28)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	64 (34.8%)
		LS Mean (SE)	-3.8 (2.21)	-1.9 (2.37)
		95% CI	-8.1, 0.6	-6.6, 2.7
		Difference from placebo		
		LS Mean (SE)	-1.8 (3.25)	
		95% CI	-8.2, 4.5	
		p-value	0.5694	
		Corrected Hedges' g (95% CI)	-0.10 (-0.43, 0.24)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	71 (38.6%)
		LS Mean (SE)	-4.5 (2.20)	-1.3 (2.33)
		95% CI	-8.8, -0.2	-5.8, 3.3
		Difference from placebo		
		LS Mean (SE)	-3.3 (3.21)	
		95% CI	-9.6, 3.0	
		p-value	0.3116	
		Corrected Hedges' g (95% CI)	-0.16 (-0.48, 0.16)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	61 (33.2%)
		LS Mean (SE)	-1.4 (2.26)	0.2 (2.44)
		95% CI	-5.8, 3.0	-4.6, 5.0
		Difference from placebo		
		LS Mean (SE)	-1.6 (3.32)	
		95% CI	-8.1, 4.9	
		p-value	0.6268	
		Corrected Hedges' g (95% CI)	-0.08 (-0.42, 0.26)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	65 (33.9%)	56 (30.4%)
		LS Mean (SE)	-3.5 (2.37)	-1.9 (2.53)
		95% CI	-8.1, 1.2	-6.9, 3.0
		Difference from placebo		
		LS Mean (SE)	-1.5 (3.48)	
		95% CI	-8.4, 5.3	
		p-value	0.6580	
		Corrected Hedges' g (95% CI)	-0.08 (-0.44, 0.28)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	57 (31.0%)
		LS Mean (SE)	-4.8 (2.36)	0.2 (2.53)
		95% CI	-9.4, -0.2	-4.7, 5.2
		Difference from placebo		
		LS Mean (SE)	-5.0 (3.47)	
		95% CI	-11.8, 1.8	
		p-value	0.1473	
		Corrected Hedges' g (95% CI)	-0.26 (-0.61, 0.09)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	49 (26.6%)
		LS Mean (SE)	-5.1 (2.54)	-1.8 (2.66)
		95% CI	-10.0, -0.1	-7.0, 3.4
		Difference from placebo		
		LS Mean (SE)	-3.3 (3.68)	
		95% CI	-10.5, 3.9	
		p-value	0.3705	
		Corrected Hedges' g (95% CI)	-0.18 (-0.57, 0.21)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	-3.8 (2.43)	2.0 (2.65)
		95% CI	-8.6, 1.0	-3.1, 7.2
		Difference from placebo		
		LS Mean (SE)	-5.8 (3.62)	
		95% CI	-12.9, 1.3	
		p-value	0.1065	
		Corrected Hedges' g (95% CI)	-0.30 (-0.67, 0.07)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	-6.1 (2.56)	0.2 (2.80)
		95% CI	-11.1, -1.0	-5.3, 5.6
		Difference from placebo		
		LS Mean (SE)	-6.2 (3.81)	
		95% CI	-13.7, 1.2	
		p-value	0.1025	
		Corrected Hedges' g (95% CI)	-0.33 (-0.74, 0.07)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	-7.2 (2.62)	-0.7 (2.69)
		95% CI	-12.4, -2.1	-6.0, 4.6
		Difference from placebo		
		LS Mean (SE)	-6.5 (3.79)	
		95% CI	-14.0, 0.9	
		p-value	0.0847	
		Corrected Hedges' g (95% CI)	-0.34 (-0.73, 0.05)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	42 (22.8%)
		LS Mean (SE)	-3.9 (2.66)	-1.9 (2.83)
		95% CI	-9.2, 1.3	-7.5, 3.6
		Difference from placebo		
		LS Mean (SE)	-2.0 (3.89)	
		95% CI	-9.7, 5.6	
		p-value	0.6022	
		Corrected Hedges' g (95% CI)	-0.11 (-0.52, 0.30)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	50 (27.2%)
		LS Mean (SE)	-5.2 (2.65)	-2.6 (2.69)
		95% CI	-10.4, -0.0	-7.9, 2.6
		Difference from placebo		
		LS Mean (SE)	-2.6 (3.79)	
		95% CI	-10.0, 4.9	
		p-value	0.4979	
		Corrected Hedges' g (95% CI)	-0.13 (-0.53, 0.26)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	43 (23.4%)
		LS Mean (SE)	-3.6 (2.79)	-2.9 (2.85)
		95% CI	-9.1, 1.9	-8.5, 2.6
		Difference from placebo		
		LS Mean (SE)	-0.7 (4.03)	
		95% CI	-8.6, 7.2	
		p-value	0.8667	
		Corrected Hedges' g (95% CI)	-0.04 (-0.46, 0.38)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	-5.5 (2.76)	-5.1 (2.86)
		95% CI	-10.9, -0.0	-10.7, 0.5
		Difference from placebo		
		LS Mean (SE)	-0.4 (4.01)	
		95% CI	-8.2, 7.5	
		p-value	0.9250	
		Corrected Hedges' g (95% CI)	-0.02 (-0.44, 0.40)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	-3.4 (2.80)	-6.7 (3.06)
		95% CI	-8.9, 2.1	-12.7, -0.7
		Difference from placebo		
		LS Mean (SE)	3.3 (4.19)	
		95% CI	-4.9, 11.5	
		p-value	0.4248	
		Corrected Hedges' g (95% CI)	0.18 (-0.26, 0.62)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	-3.1 (2.99)	0.6 (3.32)
		95% CI	-8.9, 2.8	-5.9, 7.1
		Difference from placebo		
		LS Mean (SE)	-3.6 (4.52)	
		95% CI	-12.5, 5.2	
		p-value	0.4200	
		Corrected Hedges' g (95% CI)	-0.20 (-0.68, 0.28)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	-2.1 (3.14)	-3.3 (3.64)
		95% CI	-8.3, 4.0	-10.4, 3.9
		Difference from placebo		
		LS Mean (SE)	1.1 (4.87)	
		95% CI	-8.4, 10.7	
		p-value	0.8152	
		Corrected Hedges' g (95% CI)	0.06 (-0.46, 0.58)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	-5.8 (3.47)	-2.7 (3.88)
		95% CI	-12.6, 1.0	-10.3, 4.9
		Difference from placebo		
		LS Mean (SE)	-3.1 (5.20)	
		95% CI	-13.3, 7.1	
		p-value	0.5516	
		Corrected Hedges' g (95% CI)	-0.17 (-0.75, 0.40)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	-12.4 (3.83)	1.6 (4.29)
		95% CI	-19.9, -4.9	-6.8, 10.0
		Difference from placebo		
		LS Mean (SE)	-14.1 (5.77)	
		95% CI	-25.4, -2.8	
		p-value	0.0148	
		Corrected Hedges' g (95% CI)	-0.78 (-1.44, -0.12)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	-7.9 (4.33)	-1.0 (5.18)
		95% CI	-16.4, 0.6	-11.1, 9.2
		Difference from placebo		
		LS Mean (SE)	-7.0 (6.84)	
		95% CI	-20.4, 6.5	
		p-value	0.3094	
		Corrected Hedges' g (95% CI)	-0.38 (-1.15, 0.38)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	-15.7 (5.11)	-2.9 (5.31)
		95% CI	-25.7, -5.7	-13.3, 7.5
		Difference from placebo		
		LS Mean (SE)	-12.8 (7.31)	
		95% CI	-27.2, 1.5	
		p-value	0.0791	
		Corrected Hedges' g (95% CI)	-0.70 (-1.54, 0.14)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	-9.5 (5.98)	3.8 (6.72)
		95% CI	-21.2, 2.2	-9.4, 16.9
		Difference from placebo		
		LS Mean (SE)	-13.3 (9.19)	
		95% CI	-31.3, 4.7	
		p-value	0.1484	
		Corrected Hedges' g (95% CI)	-0.68 (-1.66, 0.30)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	176 (95.7%)
		LS Mean (SE)	7.1 (1.22)	4.5 (1.32)
		95% CI	4.7, 9.5	1.9, 7.1
		Difference from placebo		
		LS Mean (SE)	2.6 (1.81)	
		95% CI	-1.0, 6.1	
		p-value	0.1551	
		Corrected Hedges' g (95% CI)	0.15 (-0.06, 0.36)	
Week 4	Change from Baseline	n (%)	177 (92.2%)	174 (94.6%)
		LS Mean (SE)	6.1 (1.59)	3.4 (1.60)
		95% CI	3.0, 9.2	0.2, 6.5
		Difference from placebo		
		LS Mean (SE)	2.8 (2.25)	
		95% CI	-1.6, 7.2	
		p-value	0.2192	
		Corrected Hedges' g (95% CI)	0.13 (-0.08, 0.34)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	169 (88.0%)	163 (88.6%)
		LS Mean (SE)	7.4 (1.60)	4.3 (1.63)
		95% CI	4.3, 10.6	1.1, 7.5
		Difference from placebo		
		LS Mean (SE)	3.2 (2.28)	
		95% CI	-1.3, 7.7	
		p-value	0.1628	
		Corrected Hedges' g (95% CI)	0.15 (-0.06, 0.37)	
Week 10	Change from Baseline	n (%)	166 (86.5%)	155 (84.2%)
		LS Mean (SE)	11.3 (1.61)	7.0 (1.65)
		95% CI	8.2, 14.5	3.7, 10.2
		Difference from placebo		
		LS Mean (SE)	4.3 (2.31)	
		95% CI	-0.2, 8.8	
		p-value	0.0608	
		Corrected Hedges' g (95% CI)	0.21 (-0.01, 0.43)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	149 (81.0%)
		LS Mean (SE)	12.1 (1.63)	8.1 (1.67)
		95% CI	8.9, 15.3	4.8, 11.3
		Difference from placebo		
		LS Mean (SE)	4.1 (2.33)	
		95% CI	-0.5, 8.6	
		p-value	0.0822	
		Corrected Hedges' g (95% CI)	0.20 (-0.03, 0.42)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	149 (81.0%)
		LS Mean (SE)	14.8 (1.65)	10.1 (1.67)
		95% CI	11.5, 18.0	6.8, 13.4
		Difference from placebo		
		LS Mean (SE)	4.6 (2.35)	
		95% CI	0.0, 9.3	
		p-value	0.0484	
		Corrected Hedges' g (95% CI)	0.23 (0.00, 0.45)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	149 (81.0%)
		LS Mean (SE)	13.7 (1.65)	9.4 (1.68)
		95% CI	10.5, 17.0	6.1, 12.7
		Difference from placebo		
		LS Mean (SE)	4.3 (2.36)	
		95% CI	-0.3, 9.0	
		p-value	0.0655	
		Corrected Hedges' g (95% CI)	0.21 (-0.01, 0.44)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	133 (72.3%)
		LS Mean (SE)	7.5 (1.71)	0.8 (1.74)
		95% CI	4.1, 10.8	-2.6, 4.2
		Difference from placebo		
		LS Mean (SE)	6.7 (2.43)	
		95% CI	1.9, 11.5	
		p-value	0.0061	
		Corrected Hedges' g (95% CI)	0.33 (0.09, 0.57)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	126 (65.6%)	131 (71.2%)
		LS Mean (SE)	5.0 (1.76)	2.3 (1.76)
		95% CI	1.5, 8.4	-1.1, 5.8
		Difference from placebo		
		LS Mean (SE)	2.7 (2.49)	
		95% CI	-2.2, 7.6	
		p-value	0.2825	
		Corrected Hedges' g (95% CI)	0.13 (-0.11, 0.38)	
Week 37	Change from Baseline	n (%)	114 (59.4%)	106 (57.6%)
		LS Mean (SE)	1.4 (1.82)	2.8 (1.87)
		95% CI	-2.2, 5.0	-0.9, 6.4
		Difference from placebo		
		LS Mean (SE)	-1.4 (2.61)	
		95% CI	-6.5, 3.7	
		p-value	0.5962	
		Corrected Hedges' g (95% CI)	-0.07 (-0.34, 0.19)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	104 (54.2%)	106 (57.6%)
		LS Mean (SE)	3.1 (1.88)	0.6 (1.90)
		95% CI	-0.6, 6.7	-3.1, 4.4
		Difference from placebo		
		LS Mean (SE)	2.4 (2.67)	
		95% CI	-2.8, 7.7	
		p-value	0.3650	
		Corrected Hedges' g (95% CI)	0.12 (-0.15, 0.40)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	83 (45.1%)
		LS Mean (SE)	3.5 (1.96)	2.2 (2.03)
		95% CI	-0.4, 7.3	-1.8, 6.2
		Difference from placebo		
		LS Mean (SE)	1.3 (2.83)	
		95% CI	-4.2, 6.8	
		p-value	0.6469	
		Corrected Hedges' g (95% CI)	0.07 (-0.23, 0.37)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	89 (46.4%)	83 (45.1%)
		LS Mean (SE)	4.6 (1.99)	4.9 (2.06)
		95% CI	0.7, 8.5	0.8, 8.9
		Difference from placebo		
		LS Mean (SE)	-0.3 (2.87)	
		95% CI	-5.9, 5.3	
		p-value	0.9111	
		Corrected Hedges' g (95% CI)	-0.02 (-0.32, 0.28)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	65 (35.3%)
		LS Mean (SE)	2.3 (2.07)	3.3 (2.21)
		95% CI	-1.8, 6.3	-1.0, 7.7
		Difference from placebo		
		LS Mean (SE)	-1.1 (3.04)	
		95% CI	-7.0, 4.9	
		p-value	0.7236	
		Corrected Hedges' g (95% CI)	-0.06 (-0.39, 0.27)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	79 (41.1%)	72 (39.1%)
		LS Mean (SE)	4.6 (2.07)	5.2 (2.17)
		95% CI	0.5, 8.6	0.9, 9.4
		Difference from placebo		
		LS Mean (SE)	-0.6 (3.01)	
		95% CI	-6.5, 5.3	
		p-value	0.8403	
		Corrected Hedges' g (95% CI)	-0.03 (-0.35, 0.29)	
Week 73	Change from Baseline	n (%)	73 (38.0%)	62 (33.7%)
		LS Mean (SE)	4.1 (2.13)	7.4 (2.28)
		95% CI	-0.0, 8.3	3.0, 11.9
		Difference from placebo		
		LS Mean (SE)	-3.3 (3.13)	
		95% CI	-9.4, 2.8	
		p-value	0.2937	
		Corrected Hedges' g (95% CI)	-0.18 (-0.52, 0.16)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	64 (33.3%)	57 (31.0%)
		LS Mean (SE)	1.4 (2.23)	5.3 (2.36)
		95% CI	-3.0, 5.8	0.6, 9.9
		Difference from placebo		
		LS Mean (SE)	-3.8 (3.25)	
		95% CI	-10.2, 2.5	
		p-value	0.2377	
		Corrected Hedges' g (95% CI)	-0.21 (-0.57, 0.14)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	3.2 (2.22)	3.4 (2.36)
		95% CI	-1.2, 7.5	-1.3, 8.0
		Difference from placebo		
		LS Mean (SE)	-0.2 (3.25)	
		95% CI	-6.5, 6.2	
		p-value	0.9590	
		Corrected Hedges' g (95% CI)	-0.01 (-0.36, 0.34)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	49 (26.6%)
		LS Mean (SE)	4.9 (2.39)	5.6 (2.52)
		95% CI	0.3, 9.6	0.7, 10.5
		Difference from placebo		
		LS Mean (SE)	-0.6 (3.48)	
		95% CI	-7.5, 6.2	
		p-value	0.8535	
		Corrected Hedges' g (95% CI)	-0.04 (-0.42, 0.35)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	5.5 (2.29)	3.8 (2.49)
		95% CI	1.0, 10.0	-1.1, 8.7
		Difference from placebo		
		LS Mean (SE)	1.7 (3.39)	
		95% CI	-4.9, 8.4	
		p-value	0.6132	
		Corrected Hedges' g (95% CI)	0.09 (-0.27, 0.46)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	4.8 (2.40)	3.6 (2.64)
		95% CI	0.0, 9.5	-1.6, 8.7
		Difference from placebo		
		LS Mean (SE)	1.2 (3.59)	
		95% CI	-5.8, 8.2	
		p-value	0.7384	
		Corrected Hedges' g (95% CI)	0.07 (-0.33, 0.47)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	6.3 (2.46)	3.7 (2.53)
		95% CI	1.5, 11.2	-1.3, 8.7
		Difference from placebo		
		LS Mean (SE)	2.6 (3.54)	
		95% CI	-4.3, 9.6	
		p-value	0.4566	
		Corrected Hedges' g (95% CI)	0.15 (-0.24, 0.54)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	42 (22.8%)
		LS Mean (SE)	6.0 (2.51)	6.7 (2.68)
		95% CI	1.1, 11.0	1.4, 11.9
		Difference from placebo		
		LS Mean (SE)	-0.6 (3.69)	
		95% CI	-7.9, 6.6	
		p-value	0.8657	
		Corrected Hedges' g (95% CI)	-0.04 (-0.45, 0.38)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	50 (27.2%)
		LS Mean (SE)	5.4 (2.50)	8.9 (2.55)
		95% CI	0.5, 10.3	3.9, 13.9
		Difference from placebo		
		LS Mean (SE)	-3.5 (3.58)	
		95% CI	-10.5, 3.5	
		p-value	0.3291	
		Corrected Hedges' g (95% CI)	-0.19 (-0.59, 0.20)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	42 (22.8%)
		LS Mean (SE)	2.3 (2.62)	6.1 (2.69)
		95% CI	-2.8, 7.4	0.9, 11.4
		Difference from placebo		
		LS Mean (SE)	-3.8 (3.77)	
		95% CI	-11.2, 3.6	
		p-value	0.3083	
		Corrected Hedges' g (95% CI)	-0.22 (-0.64, 0.21)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	3.2 (2.59)	10.8 (2.69)
		95% CI	-1.9, 8.3	5.5, 16.0
		Difference from placebo		
		LS Mean (SE)	-7.6 (3.74)	
		95% CI	-14.9, -0.2	
		p-value	0.0428	
		Corrected Hedges' g (95% CI)	-0.43 (-0.85, -0.01)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	6.7 (2.62)	9.0 (2.89)
		95% CI	1.5, 11.8	3.3, 14.7
		Difference from placebo		
		LS Mean (SE)	-2.3 (3.92)	
		95% CI	-10.0, 5.4	
		p-value	0.5554	
		Corrected Hedges' g (95% CI)	-0.13 (-0.57, 0.31)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	7.8 (2.81)	4.7 (3.17)
		95% CI	2.3, 13.3	-1.5, 10.9
		Difference from placebo		
		LS Mean (SE)	3.1 (4.25)	
		95% CI	-5.2, 11.4	
		p-value	0.4659	
		Corrected Hedges' g (95% CI)	0.18 (-0.30, 0.65)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	4.8 (2.96)	4.5 (3.47)
		95% CI	-1.0, 10.6	-2.3, 11.3
		Difference from placebo		
		LS Mean (SE)	0.3 (4.64)	
		95% CI	-8.8, 9.4	
		p-value	0.9480	
		Corrected Hedges' g (95% CI)	0.02 (-0.50, 0.54)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	9.0 (3.28)	6.3 (3.67)
		95% CI	2.5, 15.4	-0.9, 13.5
		Difference from placebo		
		LS Mean (SE)	2.7 (4.92)	
		95% CI	-7.0, 12.3	
		p-value	0.5893	
		Corrected Hedges' g (95% CI)	0.16 (-0.42, 0.73)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	10.4 (3.67)	2.8 (4.07)
		95% CI	3.2, 17.6	-5.2, 10.8
		Difference from placebo		
		LS Mean (SE)	7.7 (5.54)	
		95% CI	-3.2, 18.5	
		p-value	0.1671	
		Corrected Hedges' g (95% CI)	0.45 (-0.20, 1.09)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	11.5 (4.13)	-1.8 (4.99)
		95% CI	3.4, 19.5	-11.5, 8.0
		Difference from placebo		
		LS Mean (SE)	13.2 (6.63)	
		95% CI	0.2, 26.2	
		p-value	0.0466	
		Corrected Hedges' g (95% CI)	0.76 (-0.02, 1.55)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	17.0 (4.80)	-1.3 (5.19)
		95% CI	7.6, 26.4	-11.5, 8.8
		Difference from placebo		
		LS Mean (SE)	18.3 (7.08)	
		95% CI	4.4, 32.2	
		p-value	0.0098	
		Corrected Hedges' g (95% CI)	1.04 (0.17, 1.91)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	14.7 (5.57)	-3.2 (7.23)
		95% CI	3.7, 25.6	-17.4, 11.0
		Difference from placebo		
		LS Mean (SE)	17.9 (9.43)	
		95% CI	-0.6, 36.4	
		p-value	0.0580	
		Corrected Hedges' g (95% CI)	0.92 (-0.09, 1.92)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	13.8 (7.49)	2.0 (13.12)
		95% CI	-0.9, 28.4	-23.7, 27.7
		Difference from placebo		
		LS Mean (SE)	11.7 (15.85)	
		95% CI	-19.3, 42.8	
		p-value	0.4590	
		Corrected Hedges' g (95% CI)	0.58 (-1.09, 2.24)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	176 (95.7%)
		LS Mean (SE)	1.7 (0.74)	1.4 (0.80)
		95% CI	0.2, 3.1	-0.2, 2.9
		Difference from placebo		
		LS Mean (SE)	0.3 (1.09)	
		95% CI	-1.9, 2.4	
		p-value	0.7945	
		Corrected Hedges' g (95% CI)	0.03 (-0.18, 0.24)	
Week 4	Change from Baseline	n (%)	177 (92.2%)	174 (94.6%)
		LS Mean (SE)	3.9 (1.05)	2.9 (1.06)
		95% CI	1.8, 5.9	0.8, 5.0
		Difference from placebo		
		LS Mean (SE)	1.0 (1.49)	
		95% CI	-1.9, 3.9	
		p-value	0.5046	
		Corrected Hedges' g (95% CI)	0.07 (-0.14, 0.28)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	168 (87.5%)	164 (89.1%)
		LS Mean (SE)	3.6 (1.07)	0.4 (1.09)
		95% CI	1.5, 5.7	-1.8, 2.5
		Difference from placebo		
		LS Mean (SE)	3.2 (1.52)	
		95% CI	0.3, 6.2	
		p-value	0.0335	
		Corrected Hedges' g (95% CI)	0.23 (0.02, 0.45)	
Week 10	Change from Baseline	n (%)	166 (86.5%)	155 (84.2%)
		LS Mean (SE)	3.0 (1.07)	0.4 (1.11)
		95% CI	0.9, 5.1	-1.7, 2.6
		Difference from placebo		
		LS Mean (SE)	2.6 (1.54)	
		95% CI	-0.4, 5.6	
		p-value	0.0938	
		Corrected Hedges' g (95% CI)	0.19 (-0.03, 0.41)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	149 (81.0%)
		LS Mean (SE)	1.7 (1.09)	2.6 (1.12)
		95% CI	-0.5, 3.8	0.4, 4.8
		Difference from placebo		
		LS Mean (SE)	-0.9 (1.57)	
		95% CI	-4.0, 2.2	
		p-value	0.5703	
		Corrected Hedges' g (95% CI)	-0.06 (-0.29, 0.16)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	149 (81.0%)
		LS Mean (SE)	3.2 (1.11)	2.5 (1.13)
		95% CI	1.1, 5.4	0.3, 4.7
		Difference from placebo		
		LS Mean (SE)	0.7 (1.58)	
		95% CI	-2.4, 3.8	
		p-value	0.6548	
		Corrected Hedges' g (95% CI)	0.05 (-0.17, 0.28)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	149 (81.0%)
		LS Mean (SE)	2.2 (1.11)	-0.2 (1.13)
		95% CI	-0.0, 4.3	-2.5, 2.0
		Difference from placebo		
		LS Mean (SE)	2.4 (1.58)	
		95% CI	-0.7, 5.5	
		p-value	0.1282	
		Corrected Hedges' g (95% CI)	0.17 (-0.05, 0.40)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	133 (72.3%)
		LS Mean (SE)	-0.1 (1.15)	-0.4 (1.18)
		95% CI	-2.4, 2.1	-2.7, 1.9
		Difference from placebo		
		LS Mean (SE)	0.3 (1.65)	
		95% CI	-3.0, 3.5	
		p-value	0.8713	
		Corrected Hedges' g (95% CI)	0.02 (-0.22, 0.26)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	127 (66.1%)	130 (70.7%)
		LS Mean (SE)	0.9 (1.19)	-0.2 (1.19)
		95% CI	-1.5, 3.2	-2.5, 2.1
		Difference from placebo		
		LS Mean (SE)	1.1 (1.69)	
		95% CI	-2.3, 4.4	
		p-value	0.5329	
		Corrected Hedges' g (95% CI)	0.08 (-0.17, 0.32)	
Week 37	Change from Baseline	n (%)	114 (59.4%)	106 (57.6%)
		LS Mean (SE)	1.0 (1.24)	2.2 (1.28)
		95% CI	-1.4, 3.5	-0.3, 4.7
		Difference from placebo		
		LS Mean (SE)	-1.1 (1.79)	
		95% CI	-4.7, 2.4	
		p-value	0.5199	
		Corrected Hedges' g (95% CI)	-0.09 (-0.35, 0.18)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	104 (54.2%)	106 (57.6%)
		LS Mean (SE)	1.0 (1.29)	-0.0 (1.29)
		95% CI	-1.5, 3.5	-2.5, 2.5
		Difference from placebo		
		LS Mean (SE)	1.0 (1.83)	
		95% CI	-2.6, 4.6	
		p-value	0.5845	
		Corrected Hedges' g (95% CI)	0.08 (-0.20, 0.35)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	83 (45.1%)
		LS Mean (SE)	1.7 (1.35)	-0.6 (1.41)
		95% CI	-1.0, 4.4	-3.4, 2.2
		Difference from placebo		
		LS Mean (SE)	2.3 (1.96)	
		95% CI	-1.5, 6.1	
		p-value	0.2413	
		Corrected Hedges' g (95% CI)	0.18 (-0.12, 0.47)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	89 (46.4%)	83 (45.1%)
		LS Mean (SE)	0.6 (1.38)	1.3 (1.42)
		95% CI	-2.1, 3.3	-1.5, 4.1
		Difference from placebo		
		LS Mean (SE)	-0.8 (1.98)	
		95% CI	-4.6, 3.1	
		p-value	0.7026	
		Corrected Hedges' g (95% CI)	-0.06 (-0.36, 0.24)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	65 (35.3%)
		LS Mean (SE)	-1.3 (1.45)	1.9 (1.56)
		95% CI	-4.2, 1.5	-1.2, 5.0
		Difference from placebo		
		LS Mean (SE)	-3.2 (2.13)	
		95% CI	-7.4, 1.0	
		p-value	0.1317	
		Corrected Hedges' g (95% CI)	-0.25 (-0.58, 0.08)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	79 (41.1%)	72 (39.1%)
		LS Mean (SE)	-1.1 (1.44)	0.6 (1.51)
		95% CI	-4.0, 1.7	-2.3, 3.6
		Difference from placebo		
		LS Mean (SE)	-1.8 (2.09)	
		95% CI	-5.8, 2.3	
		p-value	0.4011	
		Corrected Hedges' g (95% CI)	-0.14 (-0.46, 0.18)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	62 (33.7%)
		LS Mean (SE)	-0.4 (1.49)	2.8 (1.60)
		95% CI	-3.3, 2.5	-0.4, 5.9
		Difference from placebo		
		LS Mean (SE)	-3.2 (2.18)	
		95% CI	-7.5, 1.1	
		p-value	0.1429	
		Corrected Hedges' g (95% CI)	-0.25 (-0.59, 0.09)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	64 (33.3%)	57 (31.0%)
		LS Mean (SE)	0.6 (1.58)	2.1 (1.66)
		95% CI	-2.4, 3.7	-1.1, 5.4
		Difference from placebo		
		LS Mean (SE)	-1.5 (2.29)	
		95% CI	-6.0, 3.0	
		p-value	0.5134	
		Corrected Hedges' g (95% CI)	-0.12 (-0.48, 0.24)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	-0.7 (1.55)	-0.6 (1.66)
		95% CI	-3.7, 2.3	-3.9, 2.6
		Difference from placebo		
		LS Mean (SE)	-0.1 (2.27)	
		95% CI	-4.5, 4.4	
		p-value	0.9736	
		Corrected Hedges' g (95% CI)	-0.01 (-0.36, 0.34)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	49 (26.6%)
		LS Mean (SE)	2.4 (1.72)	0.1 (1.78)
		95% CI	-0.9, 5.8	-3.4, 3.6
		Difference from placebo		
		LS Mean (SE)	2.3 (2.46)	
		95% CI	-2.5, 7.1	
		p-value	0.3485	
		Corrected Hedges' g (95% CI)	0.18 (-0.21, 0.57)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	0.9 (1.60)	0.9 (1.74)
		95% CI	-2.2, 4.0	-2.6, 4.3
		Difference from placebo		
		LS Mean (SE)	0.0 (2.36)	
		95% CI	-4.6, 4.6	
		p-value	0.9948	
		Corrected Hedges' g (95% CI)	0.00 (-0.37, 0.37)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	5.8 (1.70)	1.5 (1.88)
		95% CI	2.5, 9.1	-2.2, 5.2
		Difference from placebo		
		LS Mean (SE)	4.3 (2.53)	
		95% CI	-0.7, 9.2	
		p-value	0.0911	
		Corrected Hedges' g (95% CI)	0.34 (-0.06, 0.75)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	3.6 (1.74)	2.0 (1.76)
		95% CI	0.2, 7.0	-1.5, 5.4
		Difference from placebo		
		LS Mean (SE)	1.6 (2.48)	
		95% CI	-3.2, 6.5	
		p-value	0.5115	
		Corrected Hedges' g (95% CI)	0.13 (-0.26, 0.52)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	42 (22.8%)
		LS Mean (SE)	2.3 (1.84)	-0.5 (1.90)
		95% CI	-1.3, 5.9	-4.2, 3.3
		Difference from placebo		
		LS Mean (SE)	2.8 (2.64)	
		95% CI	-2.4, 7.9	
		p-value	0.2969	
		Corrected Hedges' g (95% CI)	0.22 (-0.20, 0.63)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	50 (27.2%)
		LS Mean (SE)	0.3 (1.79)	0.6 (1.78)
		95% CI	-3.2, 3.8	-2.9, 4.1
		Difference from placebo		
		LS Mean (SE)	-0.3 (2.51)	
		95% CI	-5.2, 4.7	
		p-value	0.9131	
		Corrected Hedges' g (95% CI)	-0.02 (-0.41, 0.37)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	42 (22.8%)
		LS Mean (SE)	0.6 (1.89)	0.5 (1.91)
		95% CI	-3.1, 4.3	-3.2, 4.2
		Difference from placebo		
		LS Mean (SE)	0.1 (2.67)	
		95% CI	-5.2, 5.3	
		p-value	0.9841	
		Corrected Hedges' g (95% CI)	0.00 (-0.42, 0.43)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	-0.2 (1.84)	1.4 (1.90)
		95% CI	-3.8, 3.4	-2.3, 5.1
		Difference from placebo		
		LS Mean (SE)	-1.6 (2.64)	
		95% CI	-6.8, 3.6	
		p-value	0.5453	
		Corrected Hedges' g (95% CI)	-0.13 (-0.54, 0.29)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	1.1 (1.89)	1.5 (2.05)
		95% CI	-2.6, 4.8	-2.5, 5.6
		Difference from placebo		
		LS Mean (SE)	-0.4 (2.78)	
		95% CI	-5.9, 5.0	
		p-value	0.8779	
		Corrected Hedges' g (95% CI)	-0.03 (-0.47, 0.40)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	-0.3 (2.03)	-0.2 (2.20)
		95% CI	-4.3, 3.6	-4.5, 4.1
		Difference from placebo		
		LS Mean (SE)	-0.2 (2.98)	
		95% CI	-6.0, 5.7	
		p-value	0.9522	
		Corrected Hedges' g (95% CI)	-0.01 (-0.49, 0.46)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	2.6 (2.08)	1.2 (2.47)
		95% CI	-1.4, 6.7	-3.7, 6.0
		Difference from placebo		
		LS Mean (SE)	1.5 (3.22)	
		95% CI	-4.8, 7.8	
		p-value	0.6451	
		Corrected Hedges' g (95% CI)	0.12 (-0.40, 0.64)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	-1.5 (2.37)	6.8 (2.64)
		95% CI	-6.1, 3.2	1.6, 12.0
		Difference from placebo		
		LS Mean (SE)	-8.3 (3.55)	
		95% CI	-15.2, -1.3	
		p-value	0.0200	
		Corrected Hedges' g (95% CI)	-0.67 (-1.26, -0.08)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	3.3 (2.65)	2.2 (2.92)
		95% CI	-1.9, 8.5	-3.5, 7.9
		Difference from placebo		
		LS Mean (SE)	1.1 (3.94)	
		95% CI	-6.6, 8.8	
		p-value	0.7828	
		Corrected Hedges' g (95% CI)	0.09 (-0.55, 0.73)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	0.7 (2.95)	4.8 (3.57)
		95% CI	-5.1, 6.5	-2.2, 11.8
		Difference from placebo		
		LS Mean (SE)	-4.1 (4.65)	
		95% CI	-13.2, 5.0	
		p-value	0.3807	
		Corrected Hedges' g (95% CI)	-0.33 (-1.09, 0.43)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	4.6 (3.50)	-2.5 (3.62)
		95% CI	-2.3, 11.4	-9.6, 4.6
		Difference from placebo		
		LS Mean (SE)	7.0 (5.01)	
		95% CI	-2.8, 16.8	
		p-value	0.1603	
		Corrected Hedges' g (95% CI)	0.56 (-0.27, 1.40)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	2.5 (4.28)	1.7 (4.22)
		95% CI	-5.9, 10.9	-6.6, 9.9
		Difference from placebo		
		LS Mean (SE)	0.8 (5.99)	
		95% CI	-10.9, 12.6	
		p-value	0.8893	
		Corrected Hedges' g (95% CI)	0.06 (-0.89, 1.02)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	8.0 (6.15)	7.0 (8.68)
		95% CI	-4.1, 20.0	-10.0, 24.0
		Difference from placebo		
		LS Mean (SE)	1.0 (11.35)	
		95% CI	-21.2, 23.3	
		p-value	0.9292	
		Corrected Hedges' g (95% CI)	0.06 (-1.58, 1.70)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	176 (95.7%)
		LS Mean (SE)	4.7 (1.29)	2.0 (1.39)
		95% CI	2.1, 7.2	-0.8, 4.7
		Difference from placebo		
		LS Mean (SE)	2.7 (1.90)	
		95% CI	-1.0, 6.4	
		p-value	0.1545	
		Corrected Hedges' g (95% CI)	0.15 (-0.06, 0.36)	
Week 4	Change from Baseline	n (%)	177 (92.2%)	174 (94.6%)
		LS Mean (SE)	-1.3 (1.71)	-1.3 (1.71)
		95% CI	-4.6, 2.1	-4.7, 2.0
		Difference from placebo		
		LS Mean (SE)	0.1 (2.41)	
		95% CI	-4.7, 4.8	
		p-value	0.9798	
		Corrected Hedges' g (95% CI)	0.00 (-0.21, 0.21)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	169 (88.0%)	165 (89.7%)
		LS Mean (SE)	-2.0 (1.73)	-5.3 (1.74)
		95% CI	-5.4, 1.3	-8.7, -1.9
		Difference from placebo		
		LS Mean (SE)	3.2 (2.45)	
		95% CI	-1.5, 8.0	
		p-value	0.1843	
		Corrected Hedges' g (95% CI)	0.14 (-0.07, 0.36)	
Week 10	Change from Baseline	n (%)	166 (86.5%)	156 (84.8%)
		LS Mean (SE)	-3.0 (1.73)	-0.9 (1.77)
		95% CI	-6.4, 0.4	-4.4, 2.5
		Difference from placebo		
		LS Mean (SE)	-2.1 (2.48)	
		95% CI	-6.9, 2.8	
		p-value	0.4019	
		Corrected Hedges' g (95% CI)	-0.09 (-0.31, 0.13)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	149 (81.0%)
		LS Mean (SE)	-0.6 (1.76)	-2.5 (1.79)
		95% CI	-4.0, 2.9	-6.0, 1.0
		Difference from placebo		
		LS Mean (SE)	1.9 (2.52)	
		95% CI	-3.0, 6.9	
		p-value	0.4440	
		Corrected Hedges' g (95% CI)	0.09 (-0.14, 0.31)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	149 (81.0%)
		LS Mean (SE)	1.9 (1.78)	0.1 (1.79)
		95% CI	-1.6, 5.4	-3.4, 3.7
		Difference from placebo		
		LS Mean (SE)	1.7 (2.53)	
		95% CI	-3.2, 6.7	
		p-value	0.4914	
		Corrected Hedges' g (95% CI)	0.08 (-0.15, 0.31)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	150 (81.5%)
		LS Mean (SE)	3.2 (1.78)	-0.2 (1.80)
		95% CI	-0.3, 6.7	-3.7, 3.4
		Difference from placebo		
		LS Mean (SE)	3.4 (2.54)	
		95% CI	-1.6, 8.4	
		p-value	0.1799	
		Corrected Hedges' g (95% CI)	0.15 (-0.07, 0.38)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	133 (72.3%)
		LS Mean (SE)	2.6 (1.84)	-1.2 (1.86)
		95% CI	-1.0, 6.2	-4.9, 2.4
		Difference from placebo		
		LS Mean (SE)	3.8 (2.63)	
		95% CI	-1.3, 9.0	
		p-value	0.1465	
		Corrected Hedges' g (95% CI)	0.18 (-0.06, 0.42)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	127 (66.1%)	132 (71.7%)
		LS Mean (SE)	2.3 (1.89)	0.8 (1.89)
		95% CI	-1.4, 6.0	-2.9, 4.5
		Difference from placebo		
		LS Mean (SE)	1.5 (2.68)	
		95% CI	-3.7, 6.8	
		p-value	0.5738	
		Corrected Hedges' g (95% CI)	0.07 (-0.17, 0.31)	
Week 37	Change from Baseline	n (%)	114 (59.4%)	106 (57.6%)
		LS Mean (SE)	1.0 (1.96)	2.2 (2.02)
		95% CI	-2.9, 4.8	-1.8, 6.2
		Difference from placebo		
		LS Mean (SE)	-1.3 (2.82)	
		95% CI	-6.8, 4.3	
		p-value	0.6546	
		Corrected Hedges' g (95% CI)	-0.06 (-0.32, 0.20)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	105 (54.7%)	106 (57.6%)
		LS Mean (SE)	0.8 (2.02)	-0.6 (2.05)
		95% CI	-3.2, 4.8	-4.7, 3.4
		Difference from placebo		
		LS Mean (SE)	1.4 (2.89)	
		95% CI	-4.2, 7.1	
		p-value	0.6171	
		Corrected Hedges' g (95% CI)	0.07 (-0.20, 0.34)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	83 (45.1%)
		LS Mean (SE)	2.9 (2.11)	0.4 (2.21)
		95% CI	-1.2, 7.1	-3.9, 4.8
		Difference from placebo		
		LS Mean (SE)	2.5 (3.07)	
		95% CI	-3.5, 8.5	
		p-value	0.4175	
		Corrected Hedges' g (95% CI)	0.12 (-0.17, 0.42)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	90 (46.9%)	83 (45.1%)
		LS Mean (SE)	4.4 (2.15)	1.6 (2.23)
		95% CI	0.2, 8.6	-2.8, 6.0
		Difference from placebo		
		LS Mean (SE)	2.8 (3.10)	
		95% CI	-3.3, 8.9	
		p-value	0.3676	
		Corrected Hedges' g (95% CI)	0.14 (-0.16, 0.44)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	65 (35.3%)
		LS Mean (SE)	3.2 (2.24)	-0.1 (2.42)
		95% CI	-1.2, 7.6	-4.8, 4.6
		Difference from placebo		
		LS Mean (SE)	3.3 (3.30)	
		95% CI	-3.1, 9.8	
		p-value	0.3126	
		Corrected Hedges' g (95% CI)	0.17 (-0.16, 0.50)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	72 (39.1%)
		LS Mean (SE)	5.1 (2.24)	4.5 (2.34)
		95% CI	0.7, 9.5	-0.1, 9.1
		Difference from placebo		
		LS Mean (SE)	0.6 (3.25)	
		95% CI	-5.8, 7.0	
		p-value	0.8515	
		Corrected Hedges' g (95% CI)	0.03 (-0.29, 0.35)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	62 (33.7%)
		LS Mean (SE)	3.9 (2.30)	5.6 (2.51)
		95% CI	-0.6, 8.4	0.6, 10.5
		Difference from placebo		
		LS Mean (SE)	-1.7 (3.40)	
		95% CI	-8.4, 5.0	
		p-value	0.6207	
		Corrected Hedges' g (95% CI)	-0.08 (-0.42, 0.25)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	65 (33.9%)	57 (31.0%)
		LS Mean (SE)	3.0 (2.41)	0.0 (2.56)
		95% CI	-1.7, 7.7	-5.0, 5.1
		Difference from placebo		
		LS Mean (SE)	3.0 (3.53)	
		95% CI	-4.0, 9.9	
		p-value	0.4032	
		Corrected Hedges' g (95% CI)	0.15 (-0.20, 0.51)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	5.8 (2.40)	3.3 (2.57)
		95% CI	1.1, 10.5	-1.8, 8.3
		Difference from placebo		
		LS Mean (SE)	2.5 (3.53)	
		95% CI	-4.4, 9.5	
		p-value	0.4711	
		Corrected Hedges' g (95% CI)	0.13 (-0.22, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	49 (26.6%)
		LS Mean (SE)	6.2 (2.60)	1.6 (2.74)
		95% CI	1.1, 11.3	-3.7, 7.0
		Difference from placebo		
		LS Mean (SE)	4.5 (3.79)	
		95% CI	-2.9, 12.0	
		p-value	0.2320	
		Corrected Hedges' g (95% CI)	0.24 (-0.15, 0.63)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	7.5 (2.47)	3.7 (2.71)
		95% CI	2.7, 12.4	-1.6, 9.0
		Difference from placebo		
		LS Mean (SE)	3.8 (3.70)	
		95% CI	-3.4, 11.1	
		p-value	0.2997	
		Corrected Hedges' g (95% CI)	0.19 (-0.17, 0.56)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	5.5 (2.60)	5.3 (2.89)
		95% CI	0.4, 10.6	-0.4, 10.9
		Difference from placebo		
		LS Mean (SE)	0.2 (3.91)	
		95% CI	-7.4, 7.9	
		p-value	0.9511	
		Corrected Hedges' g (95% CI)	0.01 (-0.39, 0.41)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	6.1 (2.70)	0.9 (2.74)
		95% CI	0.8, 11.4	-4.5, 6.3
		Difference from placebo		
		LS Mean (SE)	5.2 (3.89)	
		95% CI	-2.4, 12.8	
		p-value	0.1810	
		Corrected Hedges' g (95% CI)	0.27 (-0.12, 0.66)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	42 (22.8%)
		LS Mean (SE)	2.9 (2.71)	5.0 (2.93)
		95% CI	-2.4, 8.2	-0.7, 10.8
		Difference from placebo		
		LS Mean (SE)	-2.1 (4.01)	
		95% CI	-10.0, 5.7	
		p-value	0.5991	
		Corrected Hedges' g (95% CI)	-0.11 (-0.52, 0.30)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	50 (27.2%)
		LS Mean (SE)	3.2 (2.72)	7.3 (2.76)
		95% CI	-2.2, 8.5	1.9, 12.7
		Difference from placebo		
		LS Mean (SE)	-4.1 (3.90)	
		95% CI	-11.8, 3.5	
		p-value	0.2919	
		Corrected Hedges' g (95% CI)	-0.21 (-0.60, 0.18)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	43 (23.4%)
		LS Mean (SE)	2.1 (2.84)	2.4 (2.91)
		95% CI	-3.4, 7.7	-3.3, 8.1
		Difference from placebo		
		LS Mean (SE)	-0.3 (4.09)	
		95% CI	-8.3, 7.8	
		p-value	0.9509	
		Corrected Hedges' g (95% CI)	-0.01 (-0.43, 0.41)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	0.7 (2.81)	2.2 (2.92)
		95% CI	-4.8, 6.2	-3.5, 7.9
		Difference from placebo		
		LS Mean (SE)	-1.6 (4.06)	
		95% CI	-9.5, 6.4	
		p-value	0.7014	
		Corrected Hedges' g (95% CI)	-0.08 (-0.50, 0.33)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	6.9 (2.85)	8.4 (3.18)
		95% CI	1.4, 12.5	2.2, 14.7
		Difference from placebo		
		LS Mean (SE)	-1.5 (4.32)	
		95% CI	-9.9, 7.0	
		p-value	0.7347	
		Corrected Hedges' g (95% CI)	-0.08 (-0.51, 0.36)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	0.2 (3.05)	3.7 (3.44)
		95% CI	-5.8, 6.2	-3.0, 10.5
		Difference from placebo		
		LS Mean (SE)	-3.5 (4.59)	
		95% CI	-12.5, 5.5	
		p-value	0.4424	
		Corrected Hedges' g (95% CI)	-0.19 (-0.66, 0.29)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	6.9 (3.22)	4.9 (3.83)
		95% CI	0.6, 13.2	-2.6, 12.4
		Difference from placebo		
		LS Mean (SE)	2.0 (5.12)	
		95% CI	-8.0, 12.1	
		p-value	0.6955	
		Corrected Hedges' g (95% CI)	0.10 (-0.42, 0.62)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	8.2 (3.60)	7.8 (4.03)
		95% CI	1.2, 15.3	-0.1, 15.7
		Difference from placebo		
		LS Mean (SE)	0.4 (5.35)	
		95% CI	-10.1, 10.9	
		p-value	0.9441	
		Corrected Hedges' g (95% CI)	0.02 (-0.55, 0.60)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	8.4 (3.97)	3.2 (4.55)
		95% CI	0.6, 16.2	-5.7, 12.1
		Difference from placebo		
		LS Mean (SE)	5.2 (6.13)	
		95% CI	-6.8, 17.2	
		p-value	0.3937	
		Corrected Hedges' g (95% CI)	0.28 (-0.37, 0.92)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	8.5 (4.43)	6.7 (5.51)
		95% CI	-0.2, 17.1	-4.1, 17.5
		Difference from placebo		
		LS Mean (SE)	1.7 (7.18)	
		95% CI	-12.4, 15.8	
		p-value	0.8097	
		Corrected Hedges' g (95% CI)	0.09 (-0.67, 0.85)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	17.5 (5.25)	2.6 (5.45)
		95% CI	7.2, 27.8	-8.1, 13.3
		Difference from placebo		
		LS Mean (SE)	14.9 (7.61)	
		95% CI	-0.0, 29.8	
		p-value	0.0505	
		Corrected Hedges' g (95% CI)	0.79 (-0.06, 1.64)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	15.4 (6.28)	-3.9 (7.86)
		95% CI	3.1, 27.7	-19.3, 11.5
		Difference from placebo		
		LS Mean (SE)	19.3 (10.81)	
		95% CI	-1.9, 40.5	
		p-value	0.0738	
		Corrected Hedges' g (95% CI)	0.90 (-0.10, 1.89)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	19.4 (8.20)	-1.5 (13.25)
		95% CI	3.3, 35.4	-27.5, 24.5
		Difference from placebo		
		LS Mean (SE)	20.9 (16.11)	
		95% CI	-10.7, 52.5	
		p-value	0.1956	
		Corrected Hedges' g (95% CI)	0.95 (-0.76, 2.67)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	180 (93.8%)	176 (95.7%)
		LS Mean (SE)	6.5 (1.17)	4.0 (1.27)
		95% CI	4.2, 8.8	1.5, 6.5
		Difference from placebo		
		LS Mean (SE)	2.6 (1.71)	
		95% CI	-0.8, 5.9	
		p-value	0.1325	
		Corrected Hedges' g (95% CI)	0.16 (-0.05, 0.37)	
Week 4	Change from Baseline	n (%)	176 (91.7%)	174 (94.6%)
		LS Mean (SE)	4.9 (1.64)	2.0 (1.64)
		95% CI	1.7, 8.1	-1.2, 5.2
		Difference from placebo		
		LS Mean (SE)	2.9 (2.32)	
		95% CI	-1.7, 7.4	
		p-value	0.2119	
		Corrected Hedges' g (95% CI)	0.13 (-0.08, 0.34)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	168 (87.5%)	164 (89.1%)
		LS Mean (SE)	7.6 (1.66)	4.3 (1.68)
		95% CI	4.3, 10.8	1.0, 7.6
		Difference from placebo		
		LS Mean (SE)	3.3 (2.36)	
		95% CI	-1.3, 7.9	
		p-value	0.1649	
		Corrected Hedges' g (95% CI)	0.15 (-0.06, 0.37)	
Week 10	Change from Baseline	n (%)	165 (85.9%)	154 (83.7%)
		LS Mean (SE)	7.5 (1.67)	4.9 (1.71)
		95% CI	4.2, 10.7	1.6, 8.3
		Difference from placebo		
		LS Mean (SE)	2.6 (2.39)	
		95% CI	-2.1, 7.2	
		p-value	0.2861	
		Corrected Hedges' g (95% CI)	0.12 (-0.10, 0.34)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	147 (79.9%)
		LS Mean (SE)	9.2 (1.70)	7.6 (1.74)
		95% CI	5.9, 12.5	4.2, 11.0
		Difference from placebo		
		LS Mean (SE)	1.6 (2.43)	
		95% CI	-3.2, 6.3	
		p-value	0.5233	
		Corrected Hedges' g (95% CI)	0.07 (-0.15, 0.30)	
Week 16	Change from Baseline	n (%)	151 (78.6%)	148 (80.4%)
		LS Mean (SE)	9.7 (1.72)	9.8 (1.74)
		95% CI	6.3, 13.1	6.4, 13.2
		Difference from placebo		
		LS Mean (SE)	-0.1 (2.45)	
		95% CI	-4.9, 4.7	
		p-value	0.9587	
		Corrected Hedges' g (95% CI)	-0.01 (-0.23, 0.22)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	152 (79.2%)	149 (81.0%)
		LS Mean (SE)	10.1 (1.72)	9.5 (1.74)
		95% CI	6.8, 13.5	6.1, 13.0
		Difference from placebo		
		LS Mean (SE)	0.6 (2.45)	
		95% CI	-4.2, 5.4	
		p-value	0.8073	
		Corrected Hedges' g (95% CI)	0.03 (-0.20, 0.25)	
Week 25	Change from Baseline	n (%)	137 (71.4%)	133 (72.3%)
		LS Mean (SE)	4.7 (1.79)	5.6 (1.81)
		95% CI	1.2, 8.2	2.0, 9.1
		Difference from placebo		
		LS Mean (SE)	-0.9 (2.55)	
		95% CI	-5.9, 4.1	
		p-value	0.7274	
		Corrected Hedges' g (95% CI)	-0.04 (-0.28, 0.20)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	125 (65.1%)	131 (71.2%)
		LS Mean (SE)	5.8 (1.85)	5.5 (1.83)
		95% CI	2.2, 9.5	1.9, 9.1
		Difference from placebo		
		LS Mean (SE)	0.3 (2.61)	
		95% CI	-4.8, 5.5	
		p-value	0.8952	
		Corrected Hedges' g (95% CI)	0.02 (-0.23, 0.26)	
Week 37	Change from Baseline	n (%)	114 (59.4%)	106 (57.6%)
		LS Mean (SE)	3.3 (1.92)	6.1 (1.98)
		95% CI	-0.5, 7.1	2.2, 10.0
		Difference from placebo		
		LS Mean (SE)	-2.8 (2.76)	
		95% CI	-8.2, 2.6	
		p-value	0.3103	
		Corrected Hedges' g (95% CI)	-0.14 (-0.40, 0.13)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	103 (53.6%)	106 (57.6%)
		LS Mean (SE)	3.7 (2.00)	3.4 (2.00)
		95% CI	-0.2, 7.6	-0.5, 7.3
		Difference from placebo		
		LS Mean (SE)	0.3 (2.83)	
		95% CI	-5.2, 5.9	
		p-value	0.9081	
		Corrected Hedges' g (95% CI)	0.02 (-0.26, 0.29)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	83 (45.1%)
		LS Mean (SE)	4.4 (2.09)	3.2 (2.17)
		95% CI	0.3, 8.5	-1.1, 7.4
		Difference from placebo		
		LS Mean (SE)	1.2 (3.02)	
		95% CI	-4.7, 7.1	
		p-value	0.6940	
		Corrected Hedges' g (95% CI)	0.06 (-0.24, 0.36)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	89 (46.4%)	83 (45.1%)
		LS Mean (SE)	3.0 (2.12)	2.7 (2.19)
		95% CI	-1.2, 7.1	-1.6, 7.0
		Difference from placebo		
		LS Mean (SE)	0.3 (3.05)	
		95% CI	-5.7, 6.2	
		p-value	0.9344	
		Corrected Hedges' g (95% CI)	0.01 (-0.29, 0.31)	
Week 61	Change from Baseline	n (%)	77 (40.1%)	65 (35.3%)
		LS Mean (SE)	4.5 (2.24)	3.8 (2.39)
		95% CI	0.1, 8.8	-0.9, 8.4
		Difference from placebo		
		LS Mean (SE)	0.7 (3.29)	
		95% CI	-5.7, 7.1	
		p-value	0.8303	
		Corrected Hedges' g (95% CI)	0.04 (-0.29, 0.37)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	72 (39.1%)
		LS Mean (SE)	4.0 (2.21)	3.8 (2.31)
		95% CI	-0.3, 8.3	-0.7, 8.3
		Difference from placebo		
		LS Mean (SE)	0.2 (3.20)	
		95% CI	-6.0, 6.5	
		p-value	0.9437	
		Corrected Hedges' g (95% CI)	0.01 (-0.31, 0.33)	
Week 73	Change from Baseline	n (%)	72 (37.5%)	62 (33.7%)
		LS Mean (SE)	5.0 (2.30)	6.9 (2.45)
		95% CI	0.5, 9.5	2.1, 11.7
		Difference from placebo		
		LS Mean (SE)	-1.9 (3.36)	
		95% CI	-8.5, 4.7	
		p-value	0.5711	
		Corrected Hedges' g (95% CI)	-0.10 (-0.44, 0.24)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	65 (33.9%)	57 (31.0%)
		LS Mean (SE)	4.3 (2.40)	2.6 (2.54)
		95% CI	-0.4, 9.0	-2.4, 7.6
		Difference from placebo		
		LS Mean (SE)	1.7 (3.49)	
		95% CI	-5.1, 8.6	
		p-value	0.6228	
		Corrected Hedges' g (95% CI)	0.09 (-0.27, 0.44)	
Week 85	Change from Baseline	n (%)	66 (34.4%)	58 (31.5%)
		LS Mean (SE)	5.4 (2.40)	3.0 (2.54)
		95% CI	0.7, 10.1	-1.9, 8.0
		Difference from placebo		
		LS Mean (SE)	2.4 (3.50)	
		95% CI	-4.5, 9.2	
		p-value	0.4939	
		Corrected Hedges' g (95% CI)	0.12 (-0.23, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	48 (26.1%)
		LS Mean (SE)	7.5 (2.60)	3.1 (2.73)
		95% CI	2.4, 12.6	-2.2, 8.5
		Difference from placebo		
		LS Mean (SE)	4.4 (3.77)	
		95% CI	-3.0, 11.8	
		p-value	0.2457	
		Corrected Hedges' g (95% CI)	0.23 (-0.16, 0.62)	
Week 97	Change from Baseline	n (%)	62 (32.3%)	52 (28.3%)
		LS Mean (SE)	4.2 (2.46)	2.3 (2.67)
		95% CI	-0.6, 9.0	-3.0, 7.5
		Difference from placebo		
		LS Mean (SE)	1.9 (3.63)	
		95% CI	-5.2, 9.0	
		p-value	0.5979	
		Corrected Hedges' g (95% CI)	0.10 (-0.27, 0.47)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	8.5 (2.60)	0.7 (2.86)
		95% CI	3.4, 13.6	-4.9, 6.3
		Difference from placebo		
		LS Mean (SE)	7.8 (3.87)	
		95% CI	0.2, 15.4	
		p-value	0.0433	
		Corrected Hedges' g (95% CI)	0.41 (0.00, 0.81)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	8.2 (2.67)	4.7 (2.70)
		95% CI	2.9, 13.4	-0.6, 10.0
		Difference from placebo		
		LS Mean (SE)	3.4 (3.80)	
		95% CI	-4.0, 10.9	
		p-value	0.3648	
		Corrected Hedges' g (95% CI)	0.18 (-0.21, 0.57)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	48 (25.0%)	42 (22.8%)
		LS Mean (SE)	13.8 (2.75)	8.6 (2.90)
		95% CI	8.4, 19.2	2.9, 14.3
		Difference from placebo		
		LS Mean (SE)	5.2 (3.99)	
		95% CI	-2.6, 13.0	
		p-value	0.1947	
		Corrected Hedges' g (95% CI)	0.27 (-0.15, 0.69)	
Week 121	Change from Baseline	n (%)	49 (25.5%)	50 (27.2%)
		LS Mean (SE)	8.8 (2.73)	5.9 (2.72)
		95% CI	3.4, 14.1	0.6, 11.3
		Difference from placebo		
		LS Mean (SE)	2.8 (3.85)	
		95% CI	-4.7, 10.4	
		p-value	0.4633	
		Corrected Hedges' g (95% CI)	0.15 (-0.25, 0.54)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	42 (22.8%)
		LS Mean (SE)	6.3 (2.84)	5.8 (2.91)
		95% CI	0.7, 11.9	0.1, 11.5
		Difference from placebo		
		LS Mean (SE)	0.5 (4.07)	
		95% CI	-7.5, 8.4	
		p-value	0.9101	
		Corrected Hedges' g (95% CI)	0.02 (-0.40, 0.45)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	2.2 (2.81)	4.6 (2.91)
		95% CI	-3.3, 7.8	-1.1, 10.3
		Difference from placebo		
		LS Mean (SE)	-2.3 (4.05)	
		95% CI	-10.3, 5.6	
		p-value	0.5661	
		Corrected Hedges' g (95% CI)	-0.12 (-0.54, 0.30)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	6.4 (2.85)	3.8 (3.13)
		95% CI	0.9, 12.0	-2.3, 9.9
		Difference from placebo		
		LS Mean (SE)	2.6 (4.22)	
		95% CI	-5.6, 10.9	
		p-value	0.5322	
		Corrected Hedges' g (95% CI)	0.14 (-0.30, 0.58)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	10.0 (3.12)	7.2 (3.55)
		95% CI	3.9, 16.1	0.3, 14.2
		Difference from placebo		
		LS Mean (SE)	2.7 (4.59)	
		95% CI	-6.3, 11.8	
		p-value	0.5497	
		Corrected Hedges' g (95% CI)	0.14 (-0.34, 0.62)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	34 (17.7%)	24 (13.0%)
		LS Mean (SE)	5.2 (3.21)	7.8 (3.90)
		95% CI	-1.1, 11.5	0.2, 15.5
		Difference from placebo		
		LS Mean (SE)	-2.7 (5.04)	
		95% CI	-12.5, 7.2	
		p-value	0.5985	
		Corrected Hedges' g (95% CI)	-0.14 (-0.66, 0.38)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	3.8 (3.84)	4.6 (4.11)
		95% CI	-3.7, 11.3	-3.5, 12.6
		Difference from placebo		
		LS Mean (SE)	-0.8 (5.45)	
		95% CI	-11.5, 9.9	
		p-value	0.8812	
		Corrected Hedges' g (95% CI)	-0.04 (-0.62, 0.53)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	20 (10.4%)	17 (9.2%)
		LS Mean (SE)	5.0 (4.15)	4.5 (4.61)
		95% CI	-3.2, 13.1	-4.5, 13.6
		Difference from placebo		
		LS Mean (SE)	0.4 (6.06)	
		95% CI	-11.4, 12.3	
		p-value	0.9423	
		Corrected Hedges' g (95% CI)	0.02 (-0.62, 0.67)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	9.3 (4.48)	2.2 (5.43)
		95% CI	0.5, 18.1	-8.5, 12.9
		Difference from placebo		
		LS Mean (SE)	7.1 (7.01)	
		95% CI	-6.6, 20.8	
		p-value	0.3112	
		Corrected Hedges' g (95% CI)	0.38 (-0.39, 1.14)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	11 (5.7%)	11 (6.0%)
		LS Mean (SE)	13.0 (5.75)	0.6 (5.73)
		95% CI	1.7, 24.2	-10.7, 11.8
		Difference from placebo		
		LS Mean (SE)	12.4 (7.80)	
		95% CI	-2.9, 27.7	
		p-value	0.1116	
		Corrected Hedges' g (95% CI)	0.63 (-0.23, 1.48)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	12.8 (6.16)	-4.1 (6.69)
		95% CI	0.7, 24.8	-17.2, 9.1
		Difference from placebo		
		LS Mean (SE)	16.8 (9.06)	
		95% CI	-1.0, 34.6	
		p-value	0.0637	
		Corrected Hedges' g (95% CI)	0.85 (-0.14, 1.85)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	0.6 (8.55)	-12.5 (14.30)
		95% CI	-16.2, 17.3	-40.5, 15.5
		Difference from placebo		
		LS Mean (SE)	13.1 (15.56)	
		95% CI	-17.4, 43.6	
		p-value	0.4000	
		Corrected Hedges' g (95% CI)	0.57 (-1.10, 2.24)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	176 (95.7%)
		LS Mean (SE)	-5.9 (1.37)	-8.5 (1.46)
		95% CI	-8.6, -3.2	-11.3, -5.6
		Difference from placebo		
		LS Mean (SE)	2.5 (1.99)	
		95% CI	-1.4, 6.5	
		p-value	0.2024	
		Corrected Hedges' g (95% CI)	0.13 (-0.07, 0.34)	
Week 4	Change from Baseline	n (%)	175 (91.1%)	174 (94.6%)
		LS Mean (SE)	-2.0 (1.84)	-2.8 (1.84)
		95% CI	-5.6, 1.6	-6.5, 0.8
		Difference from placebo		
		LS Mean (SE)	0.9 (2.60)	
		95% CI	-4.2, 6.0	
		p-value	0.7389	
		Corrected Hedges' g (95% CI)	0.04 (-0.17, 0.25)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	168 (87.5%)	163 (88.6%)
		LS Mean (SE)	-4.9 (1.86)	-5.9 (1.88)
		95% CI	-8.5, -1.2	-9.6, -2.2
		Difference from placebo		
		LS Mean (SE)	1.0 (2.64)	
		95% CI	-4.1, 6.2	
		p-value	0.6921	
		Corrected Hedges' g (95% CI)	0.04 (-0.17, 0.26)	
Week 10	Change from Baseline	n (%)	166 (86.5%)	155 (84.2%)
		LS Mean (SE)	-2.9 (1.86)	-5.5 (1.92)
		95% CI	-6.5, 0.8	-9.3, -1.7
		Difference from placebo		
		LS Mean (SE)	2.6 (2.67)	
		95% CI	-2.6, 7.9	
		p-value	0.3220	
		Corrected Hedges' g (95% CI)	0.11 (-0.11, 0.33)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	149 (81.0%)
		LS Mean (SE)	-3.1 (1.90)	-6.3 (1.94)
		95% CI	-6.9, 0.6	-10.2, -2.5
		Difference from placebo		
		LS Mean (SE)	3.2 (2.71)	
		95% CI	-2.1, 8.5	
		p-value	0.2368	
		Corrected Hedges' g (95% CI)	0.14 (-0.09, 0.36)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	149 (81.0%)
		LS Mean (SE)	-3.4 (1.92)	-2.0 (1.94)
		95% CI	-7.2, 0.4	-5.8, 1.8
		Difference from placebo		
		LS Mean (SE)	-1.4 (2.73)	
		95% CI	-6.7, 4.0	
		p-value	0.6178	
		Corrected Hedges' g (95% CI)	-0.06 (-0.28, 0.17)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	149 (81.0%)
		LS Mean (SE)	-7.4 (1.92)	-5.6 (1.95)
		95% CI	-11.1, -3.6	-9.4, -1.8
		Difference from placebo		
		LS Mean (SE)	-1.8 (2.74)	
		95% CI	-7.1, 3.6	
		p-value	0.5197	
		Corrected Hedges' g (95% CI)	-0.07 (-0.30, 0.15)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	132 (71.7%)
		LS Mean (SE)	-5.6 (1.98)	-7.1 (2.03)
		95% CI	-9.5, -1.7	-11.0, -3.1
		Difference from placebo		
		LS Mean (SE)	1.5 (2.84)	
		95% CI	-4.1, 7.1	
		p-value	0.5970	
		Corrected Hedges' g (95% CI)	0.06 (-0.17, 0.30)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	126 (65.6%)	129 (70.1%)
		LS Mean (SE)	-6.7 (2.05)	-7.4 (2.05)
		95% CI	-10.7, -2.7	-11.4, -3.4
		Difference from placebo		
		LS Mean (SE)	0.7 (2.90)	
		95% CI	-5.0, 6.4	
		p-value	0.8084	
		Corrected Hedges' g (95% CI)	0.03 (-0.22, 0.28)	
Week 37	Change from Baseline	n (%)	114 (59.4%)	106 (57.6%)
		LS Mean (SE)	-7.3 (2.13)	-10.6 (2.19)
		95% CI	-11.4, -3.1	-14.9, -6.3
		Difference from placebo		
		LS Mean (SE)	3.3 (3.05)	
		95% CI	-2.7, 9.3	
		p-value	0.2801	
		Corrected Hedges' g (95% CI)	0.15 (-0.12, 0.41)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	104 (54.2%)	106 (57.6%)
		LS Mean (SE)	-10.3 (2.20)	-7.0 (2.21)
		95% CI	-14.6, -6.0	-11.3, -2.7
		Difference from placebo		
		LS Mean (SE)	-3.3 (3.12)	
		95% CI	-9.4, 2.8	
		p-value	0.2875	
		Corrected Hedges' g (95% CI)	-0.15 (-0.42, 0.12)	
Week 49	Change from Baseline	n (%)	91 (47.4%)	83 (45.1%)
		LS Mean (SE)	-5.8 (2.31)	-7.7 (2.40)
		95% CI	-10.3, -1.2	-12.4, -3.0
		Difference from placebo		
		LS Mean (SE)	2.0 (3.33)	
		95% CI	-4.6, 8.5	
		p-value	0.5532	
		Corrected Hedges' g (95% CI)	0.09 (-0.21, 0.39)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	89 (46.4%)	83 (45.1%)
		LS Mean (SE)	-8.1 (2.34)	-8.0 (2.41)
		95% CI	-12.7, -3.5	-12.7, -3.3
		Difference from placebo		
		LS Mean (SE)	-0.1 (3.36)	
		95% CI	-6.7, 6.5	
		p-value	0.9746	
		Corrected Hedges' g (95% CI)	-0.00 (-0.30, 0.29)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	65 (35.3%)
		LS Mean (SE)	-8.8 (2.45)	-11.2 (2.63)
		95% CI	-13.6, -4.0	-16.4, -6.1
		Difference from placebo		
		LS Mean (SE)	2.5 (3.59)	
		95% CI	-4.6, 9.5	
		p-value	0.4909	
		Corrected Hedges' g (95% CI)	0.11 (-0.21, 0.44)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	79 (41.1%)	72 (39.1%)
		LS Mean (SE)	-6.2 (2.44)	-7.2 (2.55)
		95% CI	-11.0, -1.4	-12.2, -2.2
		Difference from placebo		
		LS Mean (SE)	1.0 (3.53)	
		95% CI	-5.9, 7.9	
		p-value	0.7751	
		Corrected Hedges' g (95% CI)	0.05 (-0.27, 0.37)	
Week 73	Change from Baseline	n (%)	72 (37.5%)	62 (33.7%)
		LS Mean (SE)	-9.2 (2.53)	-8.1 (2.70)
		95% CI	-14.2, -4.2	-13.4, -2.8
		Difference from placebo		
		LS Mean (SE)	-1.1 (3.69)	
		95% CI	-8.3, 6.2	
		p-value	0.7672	
		Corrected Hedges' g (95% CI)	-0.05 (-0.39, 0.29)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	64 (33.3%)	57 (31.0%)
		LS Mean (SE)	-11.2 (2.65)	-8.8 (2.79)
		95% CI	-16.4, -6.0	-14.2, -3.3
		Difference from placebo		
		LS Mean (SE)	-2.4 (3.84)	
		95% CI	-10.0, 5.1	
		p-value	0.5297	
		Corrected Hedges' g (95% CI)	-0.11 (-0.47, 0.24)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	-11.2 (2.60)	-10.0 (2.78)
		95% CI	-16.3, -6.1	-15.5, -4.6
		Difference from placebo		
		LS Mean (SE)	-1.2 (3.81)	
		95% CI	-8.7, 6.3	
		p-value	0.7503	
		Corrected Hedges' g (95% CI)	-0.06 (-0.41, 0.29)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	49 (26.6%)
		LS Mean (SE)	-6.5 (2.85)	-3.2 (2.97)
		95% CI	-12.1, -0.9	-9.0, 2.6
		Difference from placebo		
		LS Mean (SE)	-3.3 (4.12)	
		95% CI	-11.4, 4.7	
		p-value	0.4191	
		Corrected Hedges' g (95% CI)	-0.16 (-0.55, 0.23)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	-5.1 (2.68)	-8.9 (2.91)
		95% CI	-10.4, 0.1	-14.6, -3.2
		Difference from placebo		
		LS Mean (SE)	3.7 (3.96)	
		95% CI	-4.0, 11.5	
		p-value	0.3452	
		Corrected Hedges' g (95% CI)	0.18 (-0.19, 0.54)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	-13.0 (2.84)	-11.3 (3.14)
		95% CI	-18.5, -7.4	-17.5, -5.2
		Difference from placebo		
		LS Mean (SE)	-1.6 (4.23)	
		95% CI	-9.9, 6.7	
		p-value	0.7025	
		Corrected Hedges' g (95% CI)	-0.08 (-0.48, 0.32)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	-8.4 (2.91)	-9.5 (2.95)
		95% CI	-14.1, -2.6	-15.3, -3.7
		Difference from placebo		
		LS Mean (SE)	1.1 (4.14)	
		95% CI	-7.0, 9.2	
		p-value	0.7858	
		Corrected Hedges' g (95% CI)	0.05 (-0.33, 0.44)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	42 (22.8%)
		LS Mean (SE)	-4.3 (2.96)	-10.5 (3.17)
		95% CI	-10.1, 1.5	-16.7, -4.3
		Difference from placebo		
		LS Mean (SE)	6.2 (4.34)	
		95% CI	-2.3, 14.7	
		p-value	0.1505	
		Corrected Hedges' g (95% CI)	0.30 (-0.11, 0.71)	
Week 121	Change from Baseline	n (%)	49 (25.5%)	50 (27.2%)
		LS Mean (SE)	-10.9 (2.97)	-7.2 (2.97)
		95% CI	-16.8, -5.1	-13.0, -1.3
		Difference from placebo		
		LS Mean (SE)	-3.8 (4.20)	
		95% CI	-12.0, 4.5	
		p-value	0.3707	
		Corrected Hedges' g (95% CI)	-0.18 (-0.57, 0.22)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	42 (22.8%)
		LS Mean (SE)	-11.3 (3.11)	-8.6 (3.17)
		95% CI	-17.4, -5.2	-14.9, -2.4
		Difference from placebo		
		LS Mean (SE)	-2.7 (4.45)	
		95% CI	-11.4, 6.1	
		p-value	0.5511	
		Corrected Hedges' g (95% CI)	-0.13 (-0.55, 0.30)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	-6.2 (3.06)	-8.4 (3.17)
		95% CI	-12.2, -0.2	-14.7, -2.2
		Difference from placebo		
		LS Mean (SE)	2.2 (4.40)	
		95% CI	-6.4, 10.9	
		p-value	0.6103	
		Corrected Hedges' g (95% CI)	0.11 (-0.31, 0.52)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	-5.2 (3.09)	-11.1 (3.40)
		95% CI	-11.2, 0.9	-17.8, -4.4
		Difference from placebo		
		LS Mean (SE)	5.9 (4.59)	
		95% CI	-3.1, 14.9	
		p-value	0.1968	
		Corrected Hedges' g (95% CI)	0.29 (-0.15, 0.73)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	-6.8 (3.36)	-12.8 (3.66)
		95% CI	-13.4, -0.2	-20.0, -5.6
		Difference from placebo		
		LS Mean (SE)	6.0 (5.00)	
		95% CI	-3.8, 15.8	
		p-value	0.2308	
		Corrected Hedges' g (95% CI)	0.29 (-0.19, 0.77)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	-4.6 (3.44)	-6.5 (4.07)
		95% CI	-11.3, 2.2	-14.5, 1.5
		Difference from placebo		
		LS Mean (SE)	2.0 (5.33)	
		95% CI	-8.5, 12.4	
		p-value	0.7138	
		Corrected Hedges' g (95% CI)	0.10 (-0.42, 0.62)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	-7.1 (3.99)	-13.8 (4.35)
		95% CI	-14.9, 0.7	-22.3, -5.3
		Difference from placebo		
		LS Mean (SE)	6.7 (5.88)	
		95% CI	-4.8, 18.2	
		p-value	0.2558	
		Corrected Hedges' g (95% CI)	0.33 (-0.25, 0.91)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	-6.9 (4.35)	-13.3 (4.79)
		95% CI	-15.4, 1.6	-22.7, -3.9
		Difference from placebo		
		LS Mean (SE)	6.4 (6.48)	
		95% CI	-6.3, 19.1	
		p-value	0.3257	
		Corrected Hedges' g (95% CI)	0.31 (-0.33, 0.96)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	-1.7 (5.02)	-12.2 (5.85)
		95% CI	-11.5, 8.2	-23.6, -0.7
		Difference from placebo		
		LS Mean (SE)	10.5 (7.64)	
		95% CI	-4.5, 25.5	
		p-value	0.1698	
		Corrected Hedges' g (95% CI)	0.50 (-0.27, 1.27)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	0.3 (5.72)	-4.4 (5.91)
		95% CI	-10.9, 11.6	-16.0, 7.2
		Difference from placebo		
		LS Mean (SE)	4.8 (8.20)	
		95% CI	-11.3, 20.8	
		p-value	0.5610	
		Corrected Hedges' g (95% CI)	0.23 (-0.59, 1.05)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	4.8 (6.70)	-6.1 (6.89)
		95% CI	-8.3, 18.0	-19.7, 7.4
		Difference from placebo		
		LS Mean (SE)	11.0 (9.65)	
		95% CI	-7.9, 29.9	
		p-value	0.2546	
		Corrected Hedges' g (95% CI)	0.53 (-0.44, 1.50)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	4.7 (9.47)	-19.1 (14.35)
		95% CI	-13.9, 23.3	-47.2, 9.1
		Difference from placebo		
		LS Mean (SE)	23.7 (16.14)	
		95% CI	-7.9, 55.4	
		p-value	0.1412	
		Corrected Hedges' g (95% CI)	0.95 (-0.76, 2.67)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	176 (95.7%)
		LS Mean (SE)	0.5 (1.24)	1.4 (1.35)
		95% CI	-1.9, 3.0	-1.3, 4.0
		Difference from placebo		
		LS Mean (SE)	-0.9 (1.84)	
		95% CI	-4.5, 2.8	
		p-value	0.6406	
		Corrected Hedges' g (95% CI)	-0.05 (-0.26, 0.16)	
Week 4	Change from Baseline	n (%)	176 (91.7%)	174 (94.6%)
		LS Mean (SE)	2.0 (1.73)	-0.4 (1.75)
		95% CI	-1.4, 5.4	-3.8, 3.0
		Difference from placebo		
		LS Mean (SE)	2.4 (2.46)	
		95% CI	-2.4, 7.2	
		p-value	0.3303	
		Corrected Hedges' g (95% CI)	0.10 (-0.11, 0.31)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	168 (87.5%)	164 (89.1%)
		LS Mean (SE)	1.7 (1.75)	-0.1 (1.78)
		95% CI	-1.7, 5.2	-3.6, 3.3
		Difference from placebo		
		LS Mean (SE)	1.9 (2.49)	
		95% CI	-3.0, 6.8	
		p-value	0.4504	
		Corrected Hedges' g (95% CI)	0.08 (-0.13, 0.30)	
Week 10	Change from Baseline	n (%)	165 (85.9%)	155 (84.2%)
		LS Mean (SE)	2.7 (1.76)	0.9 (1.81)
		95% CI	-0.8, 6.2	-2.7, 4.4
		Difference from placebo		
		LS Mean (SE)	1.8 (2.52)	
		95% CI	-3.1, 6.8	
		p-value	0.4668	
		Corrected Hedges' g (95% CI)	0.08 (-0.14, 0.30)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	149 (81.0%)
		LS Mean (SE)	-1.7 (1.79)	3.1 (1.83)
		95% CI	-5.2, 1.8	-0.5, 6.7
		Difference from placebo		
		LS Mean (SE)	-4.8 (2.56)	
		95% CI	-9.8, 0.2	
		p-value	0.0598	
		Corrected Hedges' g (95% CI)	-0.21 (-0.44, 0.01)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	149 (81.0%)
		LS Mean (SE)	0.1 (1.81)	1.9 (1.84)
		95% CI	-3.5, 3.6	-1.7, 5.5
		Difference from placebo		
		LS Mean (SE)	-1.8 (2.58)	
		95% CI	-6.8, 3.3	
		p-value	0.4896	
		Corrected Hedges' g (95% CI)	-0.08 (-0.31, 0.15)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	149 (81.0%)
		LS Mean (SE)	3.1 (1.81)	0.1 (1.85)
		95% CI	-0.4, 6.7	-3.5, 3.7
		Difference from placebo		
		LS Mean (SE)	3.0 (2.59)	
		95% CI	-2.0, 8.1	
		p-value	0.2416	
		Corrected Hedges' g (95% CI)	0.13 (-0.09, 0.36)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	133 (72.3%)
		LS Mean (SE)	-0.7 (1.88)	-1.2 (1.91)
		95% CI	-4.3, 3.0	-5.0, 2.5
		Difference from placebo		
		LS Mean (SE)	0.5 (2.68)	
		95% CI	-4.7, 5.8	
		p-value	0.8418	
		Corrected Hedges' g (95% CI)	0.02 (-0.21, 0.26)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	126 (65.6%)	130 (70.7%)
		LS Mean (SE)	1.3 (1.94)	-1.6 (1.95)
		95% CI	-2.6, 5.1	-5.5, 2.2
		Difference from placebo		
		LS Mean (SE)	2.9 (2.75)	
		95% CI	-2.5, 8.3	
		p-value	0.2926	
		Corrected Hedges' g (95% CI)	0.13 (-0.11, 0.38)	
Week 37	Change from Baseline	n (%)	114 (59.4%)	105 (57.1%)
		LS Mean (SE)	-3.4 (2.02)	-0.4 (2.08)
		95% CI	-7.4, 0.6	-4.5, 3.7
		Difference from placebo		
		LS Mean (SE)	-3.0 (2.90)	
		95% CI	-8.7, 2.7	
		p-value	0.2985	
		Corrected Hedges' g (95% CI)	-0.14 (-0.41, 0.13)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	104 (54.2%)	106 (57.6%)
		LS Mean (SE)	-2.4 (2.09)	-0.8 (2.11)
		95% CI	-6.5, 1.7	-4.9, 3.4
		Difference from placebo		
		LS Mean (SE)	-1.7 (2.97)	
		95% CI	-7.5, 4.2	
		p-value	0.5775	
		Corrected Hedges' g (95% CI)	-0.08 (-0.35, 0.19)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	83 (45.1%)
		LS Mean (SE)	-0.5 (2.19)	-1.7 (2.28)
		95% CI	-4.8, 3.8	-6.2, 2.8
		Difference from placebo		
		LS Mean (SE)	1.2 (3.16)	
		95% CI	-5.0, 7.4	
		p-value	0.7037	
		Corrected Hedges' g (95% CI)	0.06 (-0.24, 0.35)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	89 (46.4%)	83 (45.1%)
		LS Mean (SE)	-3.4 (2.23)	2.0 (2.32)
		95% CI	-7.8, 0.9	-2.5, 6.6
		Difference from placebo		
		LS Mean (SE)	-5.5 (3.22)	
		95% CI	-11.8, 0.9	
		p-value	0.0899	
		Corrected Hedges' g (95% CI)	-0.26 (-0.56, 0.04)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	65 (35.3%)
		LS Mean (SE)	-1.8 (2.33)	0.8 (2.50)
		95% CI	-6.3, 2.8	-4.1, 5.7
		Difference from placebo		
		LS Mean (SE)	-2.5 (3.42)	
		95% CI	-9.2, 4.2	
		p-value	0.4558	
		Corrected Hedges' g (95% CI)	-0.12 (-0.45, 0.21)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	79 (41.1%)	72 (39.1%)
		LS Mean (SE)	-3.0 (2.34)	5.2 (2.46)
		95% CI	-7.6, 1.6	0.3, 10.0
		Difference from placebo		
		LS Mean (SE)	-8.1 (3.42)	
		95% CI	-14.8, -1.4	
		p-value	0.0175	
		Corrected Hedges' g (95% CI)	-0.39 (-0.71, -0.07)	
Week 73	Change from Baseline	n (%)	73 (38.0%)	62 (33.7%)
		LS Mean (SE)	-3.2 (2.41)	3.8 (2.59)
		95% CI	-7.9, 1.5	-1.3, 8.9
		Difference from placebo		
		LS Mean (SE)	-7.0 (3.53)	
		95% CI	-13.9, -0.0	
		p-value	0.0490	
		Corrected Hedges' g (95% CI)	-0.34 (-0.68, 0.00)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	64 (33.3%)	57 (31.0%)
		LS Mean (SE)	-2.4 (2.53)	2.3 (2.68)
		95% CI	-7.4, 2.6	-3.0, 7.5
		Difference from placebo		
		LS Mean (SE)	-4.7 (3.69)	
		95% CI	-11.9, 2.6	
		p-value	0.2044	
		Corrected Hedges' g (95% CI)	-0.23 (-0.59, 0.13)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	-4.0 (2.51)	0.7 (2.69)
		95% CI	-8.9, 0.9	-4.6, 6.0
		Difference from placebo		
		LS Mean (SE)	-4.7 (3.69)	
		95% CI	-11.9, 2.6	
		p-value	0.2074	
		Corrected Hedges' g (95% CI)	-0.22 (-0.58, 0.13)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	49 (26.6%)
		LS Mean (SE)	-2.1 (2.74)	-0.7 (2.89)
		95% CI	-7.4, 3.3	-6.4, 4.9
		Difference from placebo		
		LS Mean (SE)	-1.3 (4.02)	
		95% CI	-9.2, 6.5	
		p-value	0.7401	
		Corrected Hedges' g (95% CI)	-0.07 (-0.45, 0.32)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	-1.2 (2.59)	0.2 (2.84)
		95% CI	-6.3, 3.9	-5.3, 5.8
		Difference from placebo		
		LS Mean (SE)	-1.4 (3.86)	
		95% CI	-9.0, 6.2	
		p-value	0.7179	
		Corrected Hedges' g (95% CI)	-0.07 (-0.43, 0.30)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	3.2 (2.73)	-3.2 (3.03)
		95% CI	-2.2, 8.6	-9.2, 2.7
		Difference from placebo		
		LS Mean (SE)	6.4 (4.10)	
		95% CI	-1.6, 14.4	
		p-value	0.1184	
		Corrected Hedges' g (95% CI)	0.32 (-0.09, 0.72)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	0.6 (2.81)	0.3 (2.90)
		95% CI	-5.0, 6.1	-5.4, 6.0
		Difference from placebo		
		LS Mean (SE)	0.2 (4.05)	
		95% CI	-7.7, 8.2	
		p-value	0.9510	
		Corrected Hedges' g (95% CI)	0.01 (-0.38, 0.40)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	48 (25.0%)	42 (22.8%)
		LS Mean (SE)	-0.9 (2.88)	2.8 (3.09)
		95% CI	-6.5, 4.8	-3.3, 8.8
		Difference from placebo		
		LS Mean (SE)	-3.7 (4.22)	
		95% CI	-11.9, 4.6	
		p-value	0.3858	
		Corrected Hedges' g (95% CI)	-0.18 (-0.60, 0.23)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	50 (27.2%)
		LS Mean (SE)	-0.4 (2.87)	3.1 (2.91)
		95% CI	-6.0, 5.3	-2.6, 8.8
		Difference from placebo		
		LS Mean (SE)	-3.5 (4.09)	
		95% CI	-11.5, 4.6	
		p-value	0.3982	
		Corrected Hedges' g (95% CI)	-0.17 (-0.56, 0.22)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	42 (22.8%)
		LS Mean (SE)	-5.0 (2.99)	-0.6 (3.11)
		95% CI	-10.9, 0.8	-6.7, 5.5
		Difference from placebo		
		LS Mean (SE)	-4.5 (4.32)	
		95% CI	-12.9, 4.0	
		p-value	0.3026	
		Corrected Hedges' g (95% CI)	-0.22 (-0.64, 0.20)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	-1.4 (3.00)	5.5 (3.11)
		95% CI	-7.2, 4.5	-0.5, 11.6
		Difference from placebo		
		LS Mean (SE)	-6.9 (4.37)	
		95% CI	-15.5, 1.7	
		p-value	0.1142	
		Corrected Hedges' g (95% CI)	-0.34 (-0.75, 0.08)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	-1.6 (3.01)	4.8 (3.34)
		95% CI	-7.5, 4.3	-1.7, 11.4
		Difference from placebo		
		LS Mean (SE)	-6.4 (4.50)	
		95% CI	-15.2, 2.4	
		p-value	0.1566	
		Corrected Hedges' g (95% CI)	-0.31 (-0.75, 0.13)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	0.3 (3.25)	3.6 (3.59)
		95% CI	-6.0, 6.7	-3.5, 10.6
		Difference from placebo		
		LS Mean (SE)	-3.3 (4.86)	
		95% CI	-12.8, 6.3	
		p-value	0.5031	
		Corrected Hedges' g (95% CI)	-0.16 (-0.64, 0.32)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	-1.7 (3.38)	0.2 (4.07)
		95% CI	-8.3, 5.0	-7.7, 8.2
		Difference from placebo		
		LS Mean (SE)	-1.9 (5.35)	
		95% CI	-12.4, 8.6	
		p-value	0.7225	
		Corrected Hedges' g (95% CI)	-0.09 (-0.61, 0.43)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	-1.1 (3.84)	5.1 (4.48)
		95% CI	-8.7, 6.4	-3.6, 13.9
		Difference from placebo		
		LS Mean (SE)	-6.3 (6.01)	
		95% CI	-18.1, 5.5	
		p-value	0.2954	
		Corrected Hedges' g (95% CI)	-0.31 (-0.89, 0.27)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	2.1 (4.36)	0.5 (4.79)
		95% CI	-6.5, 10.6	-8.9, 9.8
		Difference from placebo		
		LS Mean (SE)	1.6 (6.61)	
		95% CI	-11.3, 14.6	
		p-value	0.8066	
		Corrected Hedges' g (95% CI)	0.08 (-0.56, 0.72)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	8.3 (4.77)	0.0 (5.71)
		95% CI	-1.1, 17.7	-11.2, 11.2
		Difference from placebo		
		LS Mean (SE)	8.3 (7.50)	
		95% CI	-6.4, 23.0	
		p-value	0.2683	
		Corrected Hedges' g (95% CI)	0.42 (-0.35, 1.18)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	6.4 (6.38)	-0.0 (6.49)
		95% CI	-6.1, 18.9	-12.7, 12.7
		Difference from placebo		
		LS Mean (SE)	6.4 (9.99)	
		95% CI	-13.1, 26.0	
		p-value	0.5196	
		Corrected Hedges' g (95% CI)	0.28 (-0.54, 1.11)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	17.6 (6.63)	6.9 (8.10)
		95% CI	4.6, 30.6	-8.9, 22.8
		Difference from placebo		
		LS Mean (SE)	10.6 (10.89)	
		95% CI	-10.7, 32.0	
		p-value	0.3292	
		Corrected Hedges' g (95% CI)	0.47 (-0.49, 1.44)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	10.2 (9.47)	4.2 (13.73)
		95% CI	-8.4, 28.8	-22.7, 31.1
		Difference from placebo		
		LS Mean (SE)	6.0 (17.51)	
		95% CI	-28.3, 40.4	
		p-value	0.7309	
		Corrected Hedges' g (95% CI)	0.24 (-1.40, 1.89)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	175 (95.1%)
		LS Mean (SE)	0.7 (1.21)	-0.1 (1.30)
		95% CI	-1.7, 3.1	-2.7, 2.4
		Difference from placebo		
		LS Mean (SE)	0.8 (1.78)	
		95% CI	-2.7, 4.3	
		p-value	0.6414	
		Corrected Hedges' g (95% CI)	0.05 (-0.16, 0.26)	
Week 4	Change from Baseline	n (%)	176 (91.7%)	173 (94.0%)
		LS Mean (SE)	7.1 (1.69)	5.1 (1.71)
		95% CI	3.8, 10.4	1.8, 8.5
		Difference from placebo		
		LS Mean (SE)	2.0 (2.40)	
		95% CI	-2.7, 6.7	
		p-value	0.4119	
		Corrected Hedges' g (95% CI)	0.09 (-0.12, 0.30)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	168 (87.5%)	163 (88.6%)
		LS Mean (SE)	7.5 (1.71)	4.8 (1.74)
		95% CI	4.2, 10.9	1.4, 8.2
		Difference from placebo		
		LS Mean (SE)	2.7 (2.44)	
		95% CI	-2.1, 7.5	
		p-value	0.2650	
		Corrected Hedges' g (95% CI)	0.12 (-0.09, 0.34)	
Week 10	Change from Baseline	n (%)	166 (86.5%)	154 (83.7%)
		LS Mean (SE)	5.4 (1.72)	3.9 (1.78)
		95% CI	2.0, 8.8	0.5, 7.4
		Difference from placebo		
		LS Mean (SE)	1.5 (2.47)	
		95% CI	-3.4, 6.3	
		p-value	0.5565	
		Corrected Hedges' g (95% CI)	0.07 (-0.15, 0.28)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	148 (80.4%)
		LS Mean (SE)	4.4 (1.75)	2.5 (1.80)
		95% CI	0.9, 7.8	-1.1, 6.0
		Difference from placebo		
		LS Mean (SE)	1.9 (2.51)	
		95% CI	-3.0, 6.8	
		p-value	0.4467	
		Corrected Hedges' g (95% CI)	0.09 (-0.14, 0.31)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	148 (80.4%)
		LS Mean (SE)	4.5 (1.77)	2.7 (1.81)
		95% CI	1.0, 8.0	-0.8, 6.3
		Difference from placebo		
		LS Mean (SE)	1.8 (2.53)	
		95% CI	-3.2, 6.8	
		p-value	0.4762	
		Corrected Hedges' g (95% CI)	0.08 (-0.14, 0.31)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	148 (80.4%)
		LS Mean (SE)	2.7 (1.77)	-2.0 (1.81)
		95% CI	-0.8, 6.1	-5.5, 1.6
		Difference from placebo		
		LS Mean (SE)	4.6 (2.54)	
		95% CI	-0.4, 9.6	
		p-value	0.0685	
		Corrected Hedges' g (95% CI)	0.21 (-0.02, 0.44)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	131 (71.2%)
		LS Mean (SE)	-0.6 (1.84)	-1.8 (1.89)
		95% CI	-4.2, 3.0	-5.5, 1.9
		Difference from placebo		
		LS Mean (SE)	1.2 (2.64)	
		95% CI	-4.0, 6.4	
		p-value	0.6536	
		Corrected Hedges' g (95% CI)	0.05 (-0.18, 0.29)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	126 (65.6%)	129 (70.1%)
		LS Mean (SE)	0.8 (1.91)	-3.0 (1.91)
		95% CI	-2.9, 4.6	-6.8, 0.7
		Difference from placebo		
		LS Mean (SE)	3.8 (2.70)	
		95% CI	-1.4, 9.1	
		p-value	0.1539	
		Corrected Hedges' g (95% CI)	0.18 (-0.07, 0.42)	
Week 37	Change from Baseline	n (%)	114 (59.4%)	105 (57.1%)
		LS Mean (SE)	-0.7 (1.99)	-0.4 (2.05)
		95% CI	-4.6, 3.2	-4.5, 3.6
		Difference from placebo		
		LS Mean (SE)	-0.3 (2.85)	
		95% CI	-5.9, 5.3	
		p-value	0.9169	
		Corrected Hedges' g (95% CI)	-0.01 (-0.28, 0.25)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	104 (54.2%)	104 (56.5%)
		LS Mean (SE)	-1.4 (2.06)	-1.6 (2.08)
		95% CI	-5.4, 2.7	-5.7, 2.5
		Difference from placebo		
		LS Mean (SE)	0.2 (2.92)	
		95% CI	-5.5, 6.0	
		p-value	0.9338	
		Corrected Hedges' g (95% CI)	0.01 (-0.26, 0.28)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	82 (44.6%)
		LS Mean (SE)	0.5 (2.15)	-2.8 (2.26)
		95% CI	-3.8, 4.7	-7.2, 1.7
		Difference from placebo		
		LS Mean (SE)	3.2 (3.12)	
		95% CI	-2.9, 9.3	
		p-value	0.3007	
		Corrected Hedges' g (95% CI)	0.16 (-0.14, 0.45)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	88 (45.8%)	81 (44.0%)
		LS Mean (SE)	-0.5 (2.20)	-2.2 (2.28)
		95% CI	-4.8, 3.9	-6.7, 2.3
		Difference from placebo		
		LS Mean (SE)	1.7 (3.18)	
		95% CI	-4.5, 8.0	
		p-value	0.5858	
		Corrected Hedges' g (95% CI)	0.08 (-0.22, 0.39)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	64 (34.8%)
		LS Mean (SE)	-1.6 (2.30)	-3.0 (2.49)
		95% CI	-6.2, 2.9	-7.9, 1.9
		Difference from placebo		
		LS Mean (SE)	1.4 (3.39)	
		95% CI	-5.3, 8.0	
		p-value	0.6883	
		Corrected Hedges' g (95% CI)	0.07 (-0.26, 0.40)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	79 (41.1%)	71 (38.6%)
		LS Mean (SE)	0.4 (2.30)	-0.1 (2.41)
		95% CI	-4.1, 5.0	-4.8, 4.6
		Difference from placebo		
		LS Mean (SE)	0.5 (3.34)	
		95% CI	-6.0, 7.1	
		p-value	0.8721	
		Corrected Hedges' g (95% CI)	0.03 (-0.29, 0.35)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	61 (33.2%)
		LS Mean (SE)	0.2 (2.36)	-1.4 (2.56)
		95% CI	-4.4, 4.8	-6.4, 3.6
		Difference from placebo		
		LS Mean (SE)	1.6 (3.49)	
		95% CI	-5.2, 8.5	
		p-value	0.6414	
		Corrected Hedges' g (95% CI)	0.08 (-0.26, 0.42)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	64 (33.3%)	56 (30.4%)
		LS Mean (SE)	1.2 (2.52)	-0.0 (2.65)
		95% CI	-3.8, 6.1	-5.2, 5.2
		Difference from placebo		
		LS Mean (SE)	1.2 (3.67)	
		95% CI	-6.0, 8.4	
		p-value	0.7476	
		Corrected Hedges' g (95% CI)	0.06 (-0.30, 0.42)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	57 (31.0%)
		LS Mean (SE)	-2.4 (2.47)	-2.1 (2.65)
		95% CI	-7.2, 2.5	-7.3, 3.1
		Difference from placebo		
		LS Mean (SE)	-0.3 (3.63)	
		95% CI	-7.4, 6.9	
		p-value	0.9445	
		Corrected Hedges' g (95% CI)	-0.01 (-0.36, 0.34)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	48 (26.1%)
		LS Mean (SE)	2.8 (2.72)	1.3 (2.85)
		95% CI	-2.5, 8.1	-4.3, 6.9
		Difference from placebo		
		LS Mean (SE)	1.5 (3.97)	
		95% CI	-6.3, 9.3	
		p-value	0.7090	
		Corrected Hedges' g (95% CI)	0.07 (-0.32, 0.47)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	51 (27.7%)
		LS Mean (SE)	2.5 (2.55)	-2.8 (2.79)
		95% CI	-2.5, 7.5	-8.3, 2.7
		Difference from placebo		
		LS Mean (SE)	5.3 (3.79)	
		95% CI	-2.1, 12.8	
		p-value	0.1588	
		Corrected Hedges' g (95% CI)	0.26 (-0.11, 0.63)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	41 (22.3%)
		LS Mean (SE)	2.3 (2.70)	-4.1 (3.04)
		95% CI	-3.0, 7.6	-10.1, 1.8
		Difference from placebo		
		LS Mean (SE)	6.4 (4.08)	
		95% CI	-1.6, 14.4	
		p-value	0.1148	
		Corrected Hedges' g (95% CI)	0.32 (-0.08, 0.73)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	50 (27.2%)
		LS Mean (SE)	-0.1 (2.77)	-1.7 (2.82)
		95% CI	-5.5, 5.3	-7.2, 3.8
		Difference from placebo		
		LS Mean (SE)	1.6 (3.96)	
		95% CI	-6.2, 9.3	
		p-value	0.6883	
		Corrected Hedges' g (95% CI)	0.08 (-0.31, 0.47)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	41 (22.3%)
		LS Mean (SE)	-1.7 (2.82)	0.5 (3.04)
		95% CI	-7.2, 3.9	-5.5, 6.4
		Difference from placebo		
		LS Mean (SE)	-2.1 (4.16)	
		95% CI	-10.3, 6.0	
		p-value	0.6099	
		Corrected Hedges' g (95% CI)	-0.11 (-0.52, 0.31)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	49 (26.6%)
		LS Mean (SE)	2.4 (2.83)	-0.2 (2.85)
		95% CI	-3.1, 7.9	-5.8, 5.4
		Difference from placebo		
		LS Mean (SE)	2.6 (4.04)	
		95% CI	-5.3, 10.5	
		p-value	0.5220	
		Corrected Hedges' g (95% CI)	0.13 (-0.27, 0.52)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	41 (22.3%)
		LS Mean (SE)	-1.3 (2.96)	-3.8 (3.05)
		95% CI	-7.1, 4.5	-9.8, 2.1
		Difference from placebo		
		LS Mean (SE)	2.5 (4.25)	
		95% CI	-5.8, 10.9	
		p-value	0.5531	
		Corrected Hedges' g (95% CI)	0.13 (-0.30, 0.55)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	42 (22.8%)
		LS Mean (SE)	-0.7 (2.91)	-2.4 (3.04)
		95% CI	-6.4, 5.0	-8.4, 3.5
		Difference from placebo		
		LS Mean (SE)	1.7 (4.21)	
		95% CI	-6.5, 10.0	
		p-value	0.6800	
		Corrected Hedges' g (95% CI)	0.09 (-0.33, 0.51)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	35 (19.0%)
		LS Mean (SE)	-2.4 (2.94)	1.4 (3.29)
		95% CI	-8.2, 3.3	-5.1, 7.8
		Difference from placebo		
		LS Mean (SE)	-3.8 (4.41)	
		95% CI	-12.4, 4.8	
		p-value	0.3893	
		Corrected Hedges' g (95% CI)	-0.19 (-0.63, 0.25)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	30 (16.3%)
		LS Mean (SE)	-0.6 (3.19)	0.7 (3.56)
		95% CI	-6.9, 5.6	-6.2, 7.7
		Difference from placebo		
		LS Mean (SE)	-1.3 (4.80)	
		95% CI	-10.7, 8.1	
		p-value	0.7785	
		Corrected Hedges' g (95% CI)	-0.07 (-0.55, 0.41)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	-5.2 (3.29)	-4.0 (3.97)
		95% CI	-11.6, 1.3	-11.8, 3.8
		Difference from placebo		
		LS Mean (SE)	-1.2 (5.13)	
		95% CI	-11.2, 8.9	
		p-value	0.8196	
		Corrected Hedges' g (95% CI)	-0.06 (-0.58, 0.46)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	1.0 (3.75)	-1.4 (4.18)
		95% CI	-6.3, 8.4	-9.6, 6.8
		Difference from placebo		
		LS Mean (SE)	2.4 (5.60)	
		95% CI	-8.6, 13.4	
		p-value	0.6675	
		Corrected Hedges' g (95% CI)	0.12 (-0.45, 0.70)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	-7.0 (4.15)	2.9 (4.63)
		95% CI	-15.2, 1.1	-6.1, 12.0
		Difference from placebo		
		LS Mean (SE)	-9.9 (6.24)	
		95% CI	-22.2, 2.3	
		p-value	0.1107	
		Corrected Hedges' g (95% CI)	-0.51 (-1.16, 0.14)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	-3.8 (4.76)	1.8 (5.63)
		95% CI	-13.1, 5.5	-9.2, 12.9
		Difference from placebo		
		LS Mean (SE)	-5.6 (7.28)	
		95% CI	-19.9, 8.6	
		p-value	0.4396	
		Corrected Hedges' g (95% CI)	-0.28 (-1.05, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	-0.5 (5.54)	11.3 (5.74)
		95% CI	-11.3, 10.4	0.1, 22.6
		Difference from placebo		
		LS Mean (SE)	-11.8 (8.05)	
		95% CI	-27.6, 4.0	
		p-value	0.1425	
		Corrected Hedges' g (95% CI)	-0.59 (-1.43, 0.24)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	-0.9 (6.43)	-1.4 (6.71)
		95% CI	-13.5, 11.7	-14.6, 11.7
		Difference from placebo		
		LS Mean (SE)	0.5 (9.21)	
		95% CI	-17.5, 18.6	
		p-value	0.9549	
		Corrected Hedges' g (95% CI)	0.03 (-0.93, 0.98)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	9.4 (9.04)	-1.1 (13.16)
		95% CI	-8.4, 27.1	-26.9, 24.7
		Difference from placebo		
		LS Mean (SE)	10.5 (16.31)	
		95% CI	-21.5, 42.5	
		p-value	0.5201	
		Corrected Hedges' g (95% CI)	0.44 (-1.21, 2.10)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	176 (95.7%)
		LS Mean (SE)	4.5 (0.87)	2.5 (0.94)
		95% CI	2.8, 6.2	0.7, 4.4
		Difference from placebo		
		LS Mean (SE)	2.0 (1.30)	
		95% CI	-0.6, 4.5	
		p-value	0.1307	
		Corrected Hedges' g (95% CI)	0.16 (-0.05, 0.37)	
Week 4	Change from Baseline	n (%)	177 (92.2%)	173 (94.0%)
		LS Mean (SE)	5.9 (1.32)	1.5 (1.33)
		95% CI	3.3, 8.5	-1.1, 4.1
		Difference from placebo		
		LS Mean (SE)	4.4 (1.88)	
		95% CI	0.7, 8.1	
		p-value	0.0192	
		Corrected Hedges' g (95% CI)	0.25 (0.04, 0.46)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	169 (88.0%)	165 (89.7%)
		LS Mean (SE)	1.2 (1.34)	1.4 (1.36)
		95% CI	-1.4, 3.9	-1.3, 4.0
		Difference from placebo		
		LS Mean (SE)	-0.2 (1.91)	
		95% CI	-3.9, 3.6	
		p-value	0.9343	
		Corrected Hedges' g (95% CI)	-0.01 (-0.22, 0.21)	
Week 10	Change from Baseline	n (%)	166 (86.5%)	156 (84.8%)
		LS Mean (SE)	0.9 (1.35)	1.4 (1.39)
		95% CI	-1.7, 3.6	-1.3, 4.2
		Difference from placebo		
		LS Mean (SE)	-0.5 (1.94)	
		95% CI	-4.3, 3.3	
		p-value	0.7797	
		Corrected Hedges' g (95% CI)	-0.03 (-0.25, 0.19)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	149 (81.0%)
		LS Mean (SE)	2.7 (1.38)	3.0 (1.42)
		95% CI	0.0, 5.4	0.2, 5.7
		Difference from placebo		
		LS Mean (SE)	-0.2 (1.98)	
		95% CI	-4.1, 3.6	
		p-value	0.9027	
		Corrected Hedges' g (95% CI)	-0.01 (-0.24, 0.21)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	148 (80.4%)
		LS Mean (SE)	2.1 (1.40)	2.4 (1.42)
		95% CI	-0.6, 4.8	-0.4, 5.2
		Difference from placebo		
		LS Mean (SE)	-0.3 (1.99)	
		95% CI	-4.2, 3.6	
		p-value	0.8738	
		Corrected Hedges' g (95% CI)	-0.02 (-0.24, 0.21)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	150 (81.5%)
		LS Mean (SE)	2.4 (1.40)	1.9 (1.42)
		95% CI	-0.3, 5.2	-0.8, 4.7
		Difference from placebo		
		LS Mean (SE)	0.5 (1.99)	
		95% CI	-3.4, 4.4	
		p-value	0.8056	
		Corrected Hedges' g (95% CI)	0.03 (-0.20, 0.25)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	132 (71.7%)
		LS Mean (SE)	1.4 (1.46)	2.9 (1.49)
		95% CI	-1.5, 4.2	-0.1, 5.8
		Difference from placebo		
		LS Mean (SE)	-1.5 (2.09)	
		95% CI	-5.6, 2.6	
		p-value	0.4728	
		Corrected Hedges' g (95% CI)	-0.09 (-0.33, 0.15)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	126 (65.6%)	132 (71.7%)
		LS Mean (SE)	0.5 (1.52)	1.9 (1.50)
		95% CI	-2.5, 3.5	-1.1, 4.8
		Difference from placebo		
		LS Mean (SE)	-1.4 (2.13)	
		95% CI	-5.5, 2.8	
		p-value	0.5264	
		Corrected Hedges' g (95% CI)	-0.08 (-0.32, 0.17)	
Week 37	Change from Baseline	n (%)	112 (58.3%)	107 (58.2%)
		LS Mean (SE)	-1.5 (1.59)	2.0 (1.63)
		95% CI	-4.6, 1.7	-1.2, 5.2
		Difference from placebo		
		LS Mean (SE)	-3.4 (2.28)	
		95% CI	-7.9, 1.0	
		p-value	0.1308	
		Corrected Hedges' g (95% CI)	-0.20 (-0.47, 0.06)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	105 (54.7%)	105 (57.1%)
		LS Mean (SE)	3.4 (1.64)	1.4 (1.65)
		95% CI	0.2, 6.7	-1.9, 4.6
		Difference from placebo		
		LS Mean (SE)	2.1 (2.33)	
		95% CI	-2.5, 6.6	
		p-value	0.3745	
		Corrected Hedges' g (95% CI)	0.12 (-0.15, 0.39)	
Week 49	Change from Baseline	n (%)	91 (47.4%)	82 (44.6%)
		LS Mean (SE)	0.8 (1.74)	5.5 (1.83)
		95% CI	-2.6, 4.2	2.0, 9.1
		Difference from placebo		
		LS Mean (SE)	-4.7 (2.52)	
		95% CI	-9.7, 0.2	
		p-value	0.0623	
		Corrected Hedges' g (95% CI)	-0.28 (-0.58, 0.02)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	90 (46.9%)	82 (44.6%)
		LS Mean (SE)	2.8 (1.76)	1.9 (1.83)
		95% CI	-0.7, 6.2	-1.7, 5.5
		Difference from placebo		
		LS Mean (SE)	0.9 (2.54)	
		95% CI	-4.1, 5.9	
		p-value	0.7274	
		Corrected Hedges' g (95% CI)	0.05 (-0.25, 0.35)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	65 (35.3%)
		LS Mean (SE)	1.8 (1.87)	4.3 (2.02)
		95% CI	-1.9, 5.5	0.4, 8.3
		Difference from placebo		
		LS Mean (SE)	-2.5 (2.75)	
		95% CI	-7.9, 2.9	
		p-value	0.3572	
		Corrected Hedges' g (95% CI)	-0.15 (-0.48, 0.18)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	72 (39.1%)
		LS Mean (SE)	1.4 (1.85)	1.3 (1.94)
		95% CI	-2.2, 5.0	-2.5, 5.1
		Difference from placebo		
		LS Mean (SE)	0.1 (2.68)	
		95% CI	-5.2, 5.3	
		p-value	0.9829	
		Corrected Hedges' g (95% CI)	0.00 (-0.31, 0.32)	
Week 73	Change from Baseline	n (%)	73 (38.0%)	62 (33.7%)
		LS Mean (SE)	1.5 (1.92)	2.7 (2.07)
		95% CI	-2.3, 5.2	-1.3, 6.8
		Difference from placebo		
		LS Mean (SE)	-1.3 (2.83)	
		95% CI	-6.8, 4.3	
		p-value	0.6498	
		Corrected Hedges' g (95% CI)	-0.08 (-0.42, 0.26)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	65 (33.9%)	57 (31.0%)
		LS Mean (SE)	2.5 (2.02)	-1.2 (2.15)
		95% CI	-1.5, 6.5	-5.4, 3.1
		Difference from placebo		
		LS Mean (SE)	3.7 (2.96)	
		95% CI	-2.1, 9.5	
		p-value	0.2138	
		Corrected Hedges' g (95% CI)	0.22 (-0.13, 0.58)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	3.4 (2.00)	2.7 (2.14)
		95% CI	-0.6, 7.3	-1.5, 6.9
		Difference from placebo		
		LS Mean (SE)	0.7 (2.93)	
		95% CI	-5.1, 6.4	
		p-value	0.8240	
		Corrected Hedges' g (95% CI)	0.04 (-0.31, 0.39)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	49 (26.6%)
		LS Mean (SE)	6.9 (2.22)	3.7 (2.31)
		95% CI	2.6, 11.3	-0.8, 8.2
		Difference from placebo		
		LS Mean (SE)	3.2 (3.20)	
		95% CI	-3.0, 9.5	
		p-value	0.3140	
		Corrected Hedges' g (95% CI)	0.20 (-0.19, 0.59)	
Week 97	Change from Baseline	n (%)	62 (32.3%)	52 (28.3%)
		LS Mean (SE)	8.1 (2.08)	2.4 (2.26)
		95% CI	4.0, 12.2	-2.1, 6.8
		Difference from placebo		
		LS Mean (SE)	5.7 (3.06)	
		95% CI	-0.3, 11.8	
		p-value	0.0610	
		Corrected Hedges' g (95% CI)	0.35 (-0.02, 0.72)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	5.1 (2.21)	2.5 (2.45)
		95% CI	0.8, 9.5	-2.3, 7.3
		Difference from placebo		
		LS Mean (SE)	2.6 (3.29)	
		95% CI	-3.9, 9.1	
		p-value	0.4295	
		Corrected Hedges' g (95% CI)	0.16 (-0.24, 0.56)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	2.8 (2.26)	1.5 (2.28)
		95% CI	-1.7, 7.2	-3.0, 5.9
		Difference from placebo		
		LS Mean (SE)	1.3 (3.21)	
		95% CI	-5.0, 7.6	
		p-value	0.6781	
		Corrected Hedges' g (95% CI)	0.08 (-0.31, 0.47)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	42 (22.8%)
		LS Mean (SE)	0.4 (2.31)	4.0 (2.47)
		95% CI	-4.1, 4.9	-0.9, 8.8
		Difference from placebo		
		LS Mean (SE)	-3.6 (3.38)	
		95% CI	-10.2, 3.1	
		p-value	0.2937	
		Corrected Hedges' g (95% CI)	-0.22 (-0.63, 0.19)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	50 (27.2%)
		LS Mean (SE)	6.0 (2.29)	-0.1 (2.30)
		95% CI	1.5, 10.4	-4.6, 4.4
		Difference from placebo		
		LS Mean (SE)	6.0 (3.24)	
		95% CI	-0.3, 12.4	
		p-value	0.0634	
		Corrected Hedges' g (95% CI)	0.37 (-0.03, 0.76)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	43 (23.4%)
		LS Mean (SE)	5.5 (2.43)	3.2 (2.45)
		95% CI	0.8, 10.3	-1.6, 8.0
		Difference from placebo		
		LS Mean (SE)	2.4 (3.45)	
		95% CI	-4.4, 9.1	
		p-value	0.4956	
		Corrected Hedges' g (95% CI)	0.14 (-0.28, 0.57)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	5.4 (2.39)	6.0 (2.46)
		95% CI	0.7, 10.1	1.2, 10.8
		Difference from placebo		
		LS Mean (SE)	-0.6 (3.42)	
		95% CI	-7.3, 6.1	
		p-value	0.8546	
		Corrected Hedges' g (95% CI)	-0.04 (-0.45, 0.38)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	44 (22.9%)	36 (19.6%)
		LS Mean (SE)	-0.2 (2.44)	5.9 (2.67)
		95% CI	-5.0, 4.5	0.7, 11.1
		Difference from placebo		
		LS Mean (SE)	-6.2 (3.62)	
		95% CI	-13.2, 0.9	
		p-value	0.0885	
		Corrected Hedges' g (95% CI)	-0.38 (-0.82, 0.07)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	5.9 (2.73)	3.3 (2.99)
		95% CI	0.5, 11.3	-2.6, 9.1
		Difference from placebo		
		LS Mean (SE)	2.6 (3.89)	
		95% CI	-5.0, 10.2	
		p-value	0.5007	
		Corrected Hedges' g (95% CI)	0.16 (-0.32, 0.63)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	7.8 (2.71)	4.3 (3.27)
		95% CI	2.5, 13.1	-2.1, 10.7
		Difference from placebo		
		LS Mean (SE)	3.5 (4.27)	
		95% CI	-4.9, 11.9	
		p-value	0.4115	
		Corrected Hedges' g (95% CI)	0.22 (-0.31, 0.74)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	0.2 (3.11)	1.2 (3.60)
		95% CI	-5.9, 6.3	-5.8, 8.3
		Difference from placebo		
		LS Mean (SE)	-1.0 (4.71)	
		95% CI	-10.3, 8.2	
		p-value	0.8238	
		Corrected Hedges' g (95% CI)	-0.06 (-0.64, 0.51)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	5.8 (3.46)	-0.9 (3.96)
		95% CI	-0.9, 12.6	-8.7, 6.8
		Difference from placebo		
		LS Mean (SE)	6.8 (5.19)	
		95% CI	-3.4, 16.9	
		p-value	0.1921	
		Corrected Hedges' g (95% CI)	0.41 (-0.23, 1.06)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	5.3 (3.89)	10.3 (4.69)
		95% CI	-2.4, 12.9	1.1, 19.5
		Difference from placebo		
		LS Mean (SE)	-5.0 (6.11)	
		95% CI	-17.0, 7.0	
		p-value	0.4134	
		Corrected Hedges' g (95% CI)	-0.31 (-1.07, 0.46)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	12.9 (4.56)	4.1 (4.82)
		95% CI	3.9, 21.8	-5.3, 13.6
		Difference from placebo		
		LS Mean (SE)	8.8 (6.61)	
		95% CI	-4.2, 21.7	
		p-value	0.1845	
		Corrected Hedges' g (95% CI)	0.53 (-0.30, 1.36)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	6.0 (5.49)	0.8 (5.91)
		95% CI	-4.7, 16.8	-10.8, 12.3
		Difference from placebo		
		LS Mean (SE)	5.3 (8.47)	
		95% CI	-11.3, 21.9	
		p-value	0.5325	
		Corrected Hedges' g (95% CI)	0.30 (-0.66, 1.26)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	35.1 (9.09)	-3.5 (11.26)
		95% CI	17.3, 53.0	-25.6, 18.5
		Difference from placebo		
		LS Mean (SE)	38.7 (15.49)	
		95% CI	8.3, 69.0	
		p-value	0.0126	
		Corrected Hedges' g (95% CI)	1.67 (-0.19, 3.53)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	180 (93.8%)	176 (95.7%)
		LS Mean (SE)	1.8 (1.22)	-2.3 (1.27)
		95% CI	-0.5, 4.2	-4.8, 0.2
		Difference from placebo		
		LS Mean (SE)	4.1 (1.77)	
		95% CI	0.7, 7.6	
		p-value	0.0193	
		Corrected Hedges' g (95% CI)	0.25 (0.04, 0.46)	
Week 4	Change from Baseline	n (%)	175 (91.1%)	174 (94.6%)
		LS Mean (SE)	1.1 (1.51)	-1.6 (1.52)
		95% CI	-1.9, 4.0	-4.6, 1.4
		Difference from placebo		
		LS Mean (SE)	2.7 (2.14)	
		95% CI	-1.6, 6.9	
		p-value	0.2161	
		Corrected Hedges' g (95% CI)	0.13 (-0.08, 0.34)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	168 (87.5%)	164 (89.1%)
		LS Mean (SE)	-0.4 (1.52)	-4.2 (1.54)
		95% CI	-3.4, 2.6	-7.2, -1.1
		Difference from placebo		
		LS Mean (SE)	3.8 (2.16)	
		95% CI	-0.5, 8.0	
		p-value	0.0815	
		Corrected Hedges' g (95% CI)	0.19 (-0.02, 0.41)	
Week 10	Change from Baseline	n (%)	164 (85.4%)	156 (84.8%)
		LS Mean (SE)	-0.2 (1.53)	-2.3 (1.56)
		95% CI	-3.2, 2.8	-5.4, 0.7
		Difference from placebo		
		LS Mean (SE)	2.1 (2.19)	
		95% CI	-2.2, 6.4	
		p-value	0.3383	
		Corrected Hedges' g (95% CI)	0.11 (-0.11, 0.33)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	156 (81.3%)	148 (80.4%)
		LS Mean (SE)	0.7 (1.55)	-1.4 (1.58)
		95% CI	-2.3, 3.7	-4.5, 1.7
		Difference from placebo		
		LS Mean (SE)	2.1 (2.21)	
		95% CI	-2.3, 6.4	
		p-value	0.3484	
		Corrected Hedges' g (95% CI)	0.11 (-0.12, 0.33)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	147 (79.9%)
		LS Mean (SE)	1.1 (1.56)	-1.7 (1.59)
		95% CI	-1.9, 4.2	-4.8, 1.4
		Difference from placebo		
		LS Mean (SE)	2.8 (2.23)	
		95% CI	-1.5, 7.2	
		p-value	0.2044	
		Corrected Hedges' g (95% CI)	0.15 (-0.08, 0.37)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	152 (79.2%)	150 (81.5%)
		LS Mean (SE)	2.3 (1.57)	-0.8 (1.59)
		95% CI	-0.7, 5.4	-4.0, 2.3
		Difference from placebo		
		LS Mean (SE)	3.2 (2.23)	
		95% CI	-1.2, 7.6	
		p-value	0.1541	
		Corrected Hedges' g (95% CI)	0.16 (-0.06, 0.39)	
Week 25	Change from Baseline	n (%)	137 (71.4%)	133 (72.3%)
		LS Mean (SE)	1.8 (1.61)	0.2 (1.64)
		95% CI	-1.4, 4.9	-3.0, 3.4
		Difference from placebo		
		LS Mean (SE)	1.6 (2.30)	
		95% CI	-3.0, 6.1	
		p-value	0.4996	
		Corrected Hedges' g (95% CI)	0.08 (-0.16, 0.32)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	127 (66.1%)	131 (71.2%)
		LS Mean (SE)	1.7 (1.65)	-0.5 (1.66)
		95% CI	-1.5, 5.0	-3.7, 2.8
		Difference from placebo		
		LS Mean (SE)	2.2 (2.34)	
		95% CI	-2.4, 6.8	
		p-value	0.3445	
		Corrected Hedges' g (95% CI)	0.12 (-0.13, 0.36)	
Week 37	Change from Baseline	n (%)	112 (58.3%)	106 (57.6%)
		LS Mean (SE)	1.4 (1.71)	-0.6 (1.76)
		95% CI	-1.9, 4.8	-4.1, 2.8
		Difference from placebo		
		LS Mean (SE)	2.1 (2.45)	
		95% CI	-2.7, 6.9	
		p-value	0.3958	
		Corrected Hedges' g (95% CI)	0.11 (-0.15, 0.38)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	105 (54.7%)	106 (57.6%)
		LS Mean (SE)	0.2 (1.76)	-2.0 (1.77)
		95% CI	-3.2, 3.7	-5.4, 1.5
		Difference from placebo		
		LS Mean (SE)	2.2 (2.50)	
		95% CI	-2.7, 7.1	
		p-value	0.3783	
		Corrected Hedges' g (95% CI)	0.12 (-0.15, 0.39)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	83 (45.1%)
		LS Mean (SE)	0.8 (1.83)	-0.7 (1.89)
		95% CI	-2.7, 4.4	-4.4, 3.0
		Difference from placebo		
		LS Mean (SE)	1.5 (2.63)	
		95% CI	-3.6, 6.7	
		p-value	0.5621	
		Corrected Hedges' g (95% CI)	0.09 (-0.21, 0.38)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	90 (46.9%)	83 (45.1%)
		LS Mean (SE)	-1.0 (1.85)	-0.1 (1.92)
		95% CI	-4.7, 2.6	-3.8, 3.7
		Difference from placebo		
		LS Mean (SE)	-1.0 (2.67)	
		95% CI	-6.2, 4.3	
		p-value	0.7154	
		Corrected Hedges' g (95% CI)	-0.06 (-0.35, 0.24)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	65 (35.3%)
		LS Mean (SE)	-0.1 (1.93)	-2.1 (2.05)
		95% CI	-3.9, 3.7	-6.1, 1.9
		Difference from placebo		
		LS Mean (SE)	2.0 (2.82)	
		95% CI	-3.6, 7.5	
		p-value	0.4838	
		Corrected Hedges' g (95% CI)	0.12 (-0.21, 0.45)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	72 (39.1%)
		LS Mean (SE)	0.9 (1.92)	-2.2 (2.01)
		95% CI	-2.8, 4.7	-6.1, 1.8
		Difference from placebo		
		LS Mean (SE)	3.1 (2.78)	
		95% CI	-2.4, 8.5	
		p-value	0.2655	
		Corrected Hedges' g (95% CI)	0.18 (-0.14, 0.50)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	62 (33.7%)
		LS Mean (SE)	1.2 (1.97)	0.1 (2.11)
		95% CI	-2.7, 5.1	-4.0, 4.3
		Difference from placebo		
		LS Mean (SE)	1.1 (2.90)	
		95% CI	-4.6, 6.8	
		p-value	0.7110	
		Corrected Hedges' g (95% CI)	0.06 (-0.27, 0.40)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	65 (33.9%)	57 (31.0%)
		LS Mean (SE)	3.6 (2.06)	-0.5 (2.17)
		95% CI	-0.5, 7.6	-4.8, 3.7
		Difference from placebo		
		LS Mean (SE)	4.1 (2.99)	
		95% CI	-1.8, 10.0	
		p-value	0.1721	
		Corrected Hedges' g (95% CI)	0.25 (-0.11, 0.60)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	57 (31.0%)
		LS Mean (SE)	1.8 (2.06)	-0.4 (2.19)
		95% CI	-2.2, 5.8	-4.7, 3.9
		Difference from placebo		
		LS Mean (SE)	2.2 (3.02)	
		95% CI	-3.7, 8.1	
		p-value	0.4616	
		Corrected Hedges' g (95% CI)	0.13 (-0.22, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	53 (27.6%)	49 (26.6%)
		LS Mean (SE)	-1.3 (2.21)	-3.7 (2.31)
		95% CI	-5.7, 3.0	-8.2, 0.9
		Difference from placebo		
		LS Mean (SE)	2.3 (3.20)	
		95% CI	-4.0, 8.6	
		p-value	0.4688	
		Corrected Hedges' g (95% CI)	0.14 (-0.25, 0.53)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	-0.7 (2.10)	-2.1 (2.29)
		95% CI	-4.8, 3.5	-6.6, 2.4
		Difference from placebo		
		LS Mean (SE)	1.5 (3.12)	
		95% CI	-4.6, 7.6	
		p-value	0.6349	
		Corrected Hedges' g (95% CI)	0.09 (-0.28, 0.46)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	43 (23.4%)
		LS Mean (SE)	6.0 (2.22)	-1.9 (2.42)
		95% CI	1.6, 10.4	-6.7, 2.8
		Difference from placebo		
		LS Mean (SE)	7.9 (3.30)	
		95% CI	1.4, 14.4	
		p-value	0.0167	
		Corrected Hedges' g (95% CI)	0.49 (0.08, 0.89)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	2.2 (2.27)	-1.9 (2.32)
		95% CI	-2.3, 6.6	-6.5, 2.6
		Difference from placebo		
		LS Mean (SE)	4.1 (3.26)	
		95% CI	-2.3, 10.5	
		p-value	0.2096	
		Corrected Hedges' g (95% CI)	0.25 (-0.14, 0.64)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	48 (25.0%)	42 (22.8%)
		LS Mean (SE)	3.2 (2.32)	1.5 (2.45)
		95% CI	-1.3, 7.8	-3.3, 6.3
		Difference from placebo		
		LS Mean (SE)	1.7 (3.38)	
		95% CI	-4.9, 8.3	
		p-value	0.6105	
		Corrected Hedges' g (95% CI)	0.11 (-0.31, 0.52)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	50 (27.2%)
		LS Mean (SE)	3.2 (2.30)	2.5 (2.34)
		95% CI	-1.3, 7.7	-2.1, 7.1
		Difference from placebo		
		LS Mean (SE)	0.7 (3.30)	
		95% CI	-5.7, 7.2	
		p-value	0.8230	
		Corrected Hedges' g (95% CI)	0.04 (-0.35, 0.44)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	43 (23.4%)
		LS Mean (SE)	6.4 (2.42)	0.2 (2.45)
		95% CI	1.6, 11.1	-4.6, 5.0
		Difference from placebo		
		LS Mean (SE)	6.2 (3.47)	
		95% CI	-0.6, 13.0	
		p-value	0.0759	
		Corrected Hedges' g (95% CI)	0.38 (-0.04, 0.80)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	1.4 (2.39)	-4.5 (2.46)
		95% CI	-3.3, 6.1	-9.3, 0.4
		Difference from placebo		
		LS Mean (SE)	5.8 (3.45)	
		95% CI	-0.9, 12.6	
		p-value	0.0910	
		Corrected Hedges' g (95% CI)	0.36 (-0.06, 0.78)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	0.5 (2.41)	-2.8 (2.64)
		95% CI	-4.3, 5.2	-7.9, 2.4
		Difference from placebo		
		LS Mean (SE)	3.2 (3.59)	
		95% CI	-3.8, 10.3	
		p-value	0.3701	
		Corrected Hedges' g (95% CI)	0.20 (-0.24, 0.64)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	4.5 (2.60)	-3.3 (2.80)
		95% CI	-0.6, 9.6	-8.8, 2.2
		Difference from placebo		
		LS Mean (SE)	7.8 (3.84)	
		95% CI	0.3, 15.3	
		p-value	0.0427	
		Corrected Hedges' g (95% CI)	0.49 (0.01, 0.97)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	-2.2 (2.71)	-3.2 (3.17)
		95% CI	-7.5, 3.1	-9.4, 3.0
		Difference from placebo		
		LS Mean (SE)	1.0 (4.26)	
		95% CI	-7.3, 9.4	
		p-value	0.8112	
		Corrected Hedges' g (95% CI)	0.06 (-0.46, 0.58)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	2.9 (3.01)	-1.8 (3.37)
		95% CI	-3.0, 8.8	-8.4, 4.8
		Difference from placebo		
		LS Mean (SE)	4.7 (4.56)	
		95% CI	-4.2, 13.7	
		p-value	0.2990	
		Corrected Hedges' g (95% CI)	0.30 (-0.28, 0.88)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	2.5 (3.31)	1.7 (3.74)
		95% CI	-4.0, 9.0	-5.6, 9.1
		Difference from placebo		
		LS Mean (SE)	0.7 (5.07)	
		95% CI	-9.2, 10.7	
		p-value	0.8852	
		Corrected Hedges' g (95% CI)	0.05 (-0.59, 0.69)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	2.4 (3.77)	-6.2 (4.45)
		95% CI	-5.0, 9.8	-14.9, 2.6
		Difference from placebo		
		LS Mean (SE)	8.5 (5.96)	
		95% CI	-3.2, 20.2	
		p-value	0.1529	
		Corrected Hedges' g (95% CI)	0.54 (-0.23, 1.31)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	-0.8 (4.33)	-5.5 (4.61)
		95% CI	-9.3, 7.7	-14.5, 3.6
		Difference from placebo		
		LS Mean (SE)	4.7 (6.34)	
		95% CI	-7.7, 17.1	
		p-value	0.4597	
		Corrected Hedges' g (95% CI)	0.30 (-0.52, 1.12)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	14.4 (5.74)	-11.4 (5.29)
		95% CI	3.1, 25.6	-21.8, -1.1
		Difference from placebo		
		LS Mean (SE)	25.8 (8.08)	
		95% CI	10.0, 41.7	
		p-value	0.0014	
		Corrected Hedges' g (95% CI)	1.51 (0.43, 2.59)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1102 Summary of Analysis of EORTC-QLQ-C30 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	1.3 (7.88)	-15.3 (10.09)
		95% CI	-14.2, 16.7	-35.1, 4.5
		Difference from placebo		
		LS Mean (SE)	16.6 (12.69)	
		95% CI	-8.3, 41.5	
		p-value	0.1920	
		Corrected Hedges' g (95% CI)	0.82 (-0.87, 2.52)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1102_c30_mmrm.sas, Output: t_2_1102_c30_mmrm.rtf, Generated on: 14AUG2024 11:25, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	168 (87.5%)	162 (88.0%)
		LS Mean (SE)	-0.3 (1.08)	2.5 (1.13)
		95% CI	-2.5, 1.8	0.3, 4.7
		Difference from placebo		
		LS Mean (SE)	-2.8 (1.56)	
		95% CI	-5.9, 0.3	
		p-value	0.0726	
		Corrected Hedges' g (95% CI)	-0.20 (-0.41, 0.02)	
Week 4	Change from Baseline	n (%)	161 (83.9%)	159 (86.4%)
		LS Mean (SE)	-2.1 (1.37)	0.6 (1.39)
		95% CI	-4.8, 0.6	-2.1, 3.4
		Difference from placebo		
		LS Mean (SE)	-2.7 (1.95)	
		95% CI	-6.5, 1.1	
		p-value	0.1614	
		Corrected Hedges' g (95% CI)	-0.16 (-0.38, 0.06)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	155 (80.7%)	147 (79.9%)
		LS Mean (SE)	0.5 (1.38)	1.2 (1.42)
		95% CI	-2.2, 3.2	-1.6, 3.9
		Difference from placebo		
		LS Mean (SE)	-0.7 (1.98)	
		95% CI	-4.6, 3.2	
		p-value	0.7304	
		Corrected Hedges' g (95% CI)	-0.04 (-0.27, 0.19)	
Week 10	Change from Baseline	n (%)	150 (78.1%)	138 (75.0%)
		LS Mean (SE)	-0.5 (1.40)	0.8 (1.44)
		95% CI	-3.2, 2.3	-2.0, 3.6
		Difference from placebo		
		LS Mean (SE)	-1.3 (2.01)	
		95% CI	-5.2, 2.7	
		p-value	0.5309	
		Corrected Hedges' g (95% CI)	-0.07 (-0.31, 0.16)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	138 (71.9%)	133 (72.3%)
		LS Mean (SE)	-1.1 (1.43)	-0.4 (1.46)
		95% CI	-3.9, 1.7	-3.2, 2.5
		Difference from placebo		
		LS Mean (SE)	-0.7 (2.05)	
		95% CI	-4.7, 3.3	
		p-value	0.7286	
		Corrected Hedges' g (95% CI)	-0.04 (-0.28, 0.20)	
Week 16	Change from Baseline	n (%)	133 (69.3%)	126 (68.5%)
		LS Mean (SE)	-4.0 (1.45)	-0.3 (1.48)
		95% CI	-6.9, -1.2	-3.2, 2.7
		Difference from placebo		
		LS Mean (SE)	-3.8 (2.07)	
		95% CI	-7.9, 0.3	
		p-value	0.0679	
		Corrected Hedges' g (95% CI)	-0.23 (-0.47, 0.02)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	133 (69.3%)	126 (68.5%)
		LS Mean (SE)	-2.9 (1.45)	2.3 (1.49)
		95% CI	-5.7, -0.0	-0.6, 5.2
		Difference from placebo		
		LS Mean (SE)	-5.2 (2.08)	
		95% CI	-9.2, -1.1	
		p-value	0.0133	
		Corrected Hedges' g (95% CI)	-0.31 (-0.55, -0.06)	
Week 25	Change from Baseline	n (%)	123 (64.1%)	117 (63.6%)
		LS Mean (SE)	-0.2 (1.49)	2.7 (1.53)
		95% CI	-3.1, 2.8	-0.3, 5.7
		Difference from placebo		
		LS Mean (SE)	-2.9 (2.13)	
		95% CI	-7.1, 1.3	
		p-value	0.1751	
		Corrected Hedges' g (95% CI)	-0.17 (-0.43, 0.08)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	114 (59.4%)	114 (62.0%)
		LS Mean (SE)	0.8 (1.53)	2.2 (1.54)
		95% CI	-2.2, 3.8	-0.8, 5.3
		Difference from placebo		
		LS Mean (SE)	-1.4 (2.17)	
		95% CI	-5.7, 2.8	
		p-value	0.5113	
		Corrected Hedges' g (95% CI)	-0.09 (-0.35, 0.17)	
Week 37	Change from Baseline	n (%)	101 (52.6%)	92 (50.0%)
		LS Mean (SE)	0.8 (1.59)	4.7 (1.65)
		95% CI	-2.3, 3.9	1.5, 8.0
		Difference from placebo		
		LS Mean (SE)	-3.9 (2.29)	
		95% CI	-8.4, 0.6	
		p-value	0.0862	
		Corrected Hedges' g (95% CI)	-0.25 (-0.53, 0.04)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	95 (49.5%)	90 (48.9%)
		LS Mean (SE)	4.4 (1.63)	1.4 (1.68)
		95% CI	1.2, 7.6	-1.9, 4.7
		Difference from placebo		
		LS Mean (SE)	2.9 (2.34)	
		95% CI	-1.7, 7.5	
		p-value	0.2122	
		Corrected Hedges' g (95% CI)	0.18 (-0.11, 0.47)	
Week 49	Change from Baseline	n (%)	82 (42.7%)	70 (38.0%)
		LS Mean (SE)	2.3 (1.71)	2.1 (1.82)
		95% CI	-1.0, 5.7	-1.5, 5.7
		Difference from placebo		
		LS Mean (SE)	0.2 (2.49)	
		95% CI	-4.6, 5.1	
		p-value	0.9203	
		Corrected Hedges' g (95% CI)	0.02 (-0.30, 0.34)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	76 (39.6%)	69 (37.5%)
		LS Mean (SE)	0.9 (1.76)	3.0 (1.83)
		95% CI	-2.6, 4.3	-0.6, 6.6
		Difference from placebo		
		LS Mean (SE)	-2.2 (2.54)	
		95% CI	-7.1, 2.8	
		p-value	0.3972	
		Corrected Hedges' g (95% CI)	-0.14 (-0.47, 0.19)	
Week 61	Change from Baseline	n (%)	69 (35.9%)	58 (31.5%)
		LS Mean (SE)	-0.6 (1.82)	6.1 (1.95)
		95% CI	-4.2, 3.0	2.3, 9.9
		Difference from placebo		
		LS Mean (SE)	-6.7 (2.67)	
		95% CI	-11.9, -1.5	
		p-value	0.0118	
		Corrected Hedges' g (95% CI)	-0.45 (-0.80, -0.09)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	71 (37.0%)	63 (34.2%)
		LS Mean (SE)	-1.5 (1.81)	1.3 (1.90)
		95% CI	-5.0, 2.1	-2.4, 5.1
		Difference from placebo		
		LS Mean (SE)	-2.8 (2.62)	
		95% CI	-7.9, 2.4	
		p-value	0.2880	
		Corrected Hedges' g (95% CI)	-0.18 (-0.52, 0.16)	
Week 73	Change from Baseline	n (%)	67 (34.9%)	54 (29.3%)
		LS Mean (SE)	0.2 (1.85)	4.6 (2.01)
		95% CI	-3.4, 3.8	0.7, 8.6
		Difference from placebo		
		LS Mean (SE)	-4.4 (2.74)	
		95% CI	-9.8, 0.9	
		p-value	0.1051	
		Corrected Hedges' g (95% CI)	-0.29 (-0.66, 0.07)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	58 (30.2%)	47 (25.5%)
		LS Mean (SE)	-0.1 (1.94)	0.2 (2.11)
		95% CI	-3.9, 3.7	-3.9, 4.4
		Difference from placebo		
		LS Mean (SE)	-0.3 (2.87)	
		95% CI	-5.9, 5.3	
		p-value	0.9200	
		Corrected Hedges' g (95% CI)	-0.02 (-0.40, 0.37)	
Week 85	Change from Baseline	n (%)	60 (31.3%)	53 (28.8%)
		LS Mean (SE)	0.5 (1.93)	0.3 (2.03)
		95% CI	-3.3, 4.3	-3.7, 4.3
		Difference from placebo		
		LS Mean (SE)	0.2 (2.81)	
		95% CI	-5.3, 5.8	
		p-value	0.9297	
		Corrected Hedges' g (95% CI)	0.02 (-0.35, 0.39)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	47 (24.5%)	44 (23.9%)
		LS Mean (SE)	2.7 (2.10)	1.6 (2.17)
		95% CI	-1.4, 6.9	-2.6, 5.9
		Difference from placebo		
		LS Mean (SE)	1.1 (3.03)	
		95% CI	-4.8, 7.0	
		p-value	0.7170	
		Corrected Hedges' g (95% CI)	0.08 (-0.34, 0.49)	
Week 97	Change from Baseline	n (%)	56 (29.2%)	49 (26.6%)
		LS Mean (SE)	-0.4 (1.99)	0.9 (2.11)
		95% CI	-4.3, 3.5	-3.2, 5.1
		Difference from placebo		
		LS Mean (SE)	-1.3 (2.91)	
		95% CI	-7.0, 4.4	
		p-value	0.6489	
		Corrected Hedges' g (95% CI)	-0.09 (-0.47, 0.29)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	50 (26.0%)	39 (21.2%)
		LS Mean (SE)	-2.4 (2.06)	3.9 (2.29)
		95% CI	-6.4, 1.6	-0.6, 8.4
		Difference from placebo		
		LS Mean (SE)	-6.3 (3.09)	
		95% CI	-12.3, -0.2	
		p-value	0.0420	
		Corrected Hedges' g (95% CI)	-0.43 (-0.85, -0.01)	
Week 109	Change from Baseline	n (%)	46 (24.0%)	44 (23.9%)
		LS Mean (SE)	0.8 (2.13)	3.3 (2.19)
		95% CI	-3.3, 5.0	-1.0, 7.6
		Difference from placebo		
		LS Mean (SE)	-2.4 (3.06)	
		95% CI	-8.4, 3.6	
		p-value	0.4289	
		Corrected Hedges' g (95% CI)	-0.17 (-0.58, 0.25)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	47 (24.5%)	38 (20.7%)
		LS Mean (SE)	-1.6 (2.12)	2.8 (2.31)
		95% CI	-5.8, 2.5	-1.7, 7.3
		Difference from placebo		
		LS Mean (SE)	-4.4 (3.13)	
		95% CI	-10.6, 1.7	
		p-value	0.1559	
		Corrected Hedges' g (95% CI)	-0.31 (-0.74, 0.12)	
Week 121	Change from Baseline	n (%)	44 (22.9%)	45 (24.5%)
		LS Mean (SE)	-0.8 (2.19)	2.2 (2.18)
		95% CI	-5.1, 3.5	-2.0, 6.5
		Difference from placebo		
		LS Mean (SE)	-3.1 (3.10)	
		95% CI	-9.1, 3.0	
		p-value	0.3253	
		Corrected Hedges' g (95% CI)	-0.21 (-0.62, 0.21)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	41 (21.4%)	38 (20.7%)
		LS Mean (SE)	-0.7 (2.24)	2.6 (2.32)
		95% CI	-5.1, 3.7	-1.9, 7.2
		Difference from placebo		
		LS Mean (SE)	-3.3 (3.22)	
		95% CI	-9.6, 3.0	
		p-value	0.3080	
		Corrected Hedges' g (95% CI)	-0.23 (-0.67, 0.22)	
Week 133	Change from Baseline	n (%)	41 (21.4%)	38 (20.7%)
		LS Mean (SE)	1.3 (2.26)	2.7 (2.33)
		95% CI	-3.2, 5.7	-1.9, 7.2
		Difference from placebo		
		LS Mean (SE)	-1.4 (3.25)	
		95% CI	-7.8, 5.0	
		p-value	0.6662	
		Corrected Hedges' g (95% CI)	-0.10 (-0.54, 0.35)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	42 (21.9%)	33 (17.9%)
		LS Mean (SE)	-2.8 (2.23)	0.5 (2.46)
		95% CI	-7.1, 1.6	-4.3, 5.3
		Difference from placebo		
		LS Mean (SE)	-3.2 (3.32)	
		95% CI	-9.7, 3.3	
		p-value	0.3295	
		Corrected Hedges' g (95% CI)	-0.22 (-0.68, 0.23)	
Week 145	Change from Baseline	n (%)	33 (17.2%)	27 (14.7%)
		LS Mean (SE)	7.1 (2.46)	2.3 (2.68)
		95% CI	2.3, 11.9	-3.0, 7.5
		Difference from placebo		
		LS Mean (SE)	4.8 (3.63)	
		95% CI	-2.3, 11.9	
		p-value	0.1869	
		Corrected Hedges' g (95% CI)	0.34 (-0.18, 0.85)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	32 (16.7%)	23 (12.5%)
		LS Mean (SE)	1.4 (2.51)	4.6 (2.88)
		95% CI	-3.5, 6.3	-1.1, 10.2
		Difference from placebo		
		LS Mean (SE)	-3.1 (3.83)	
		95% CI	-10.6, 4.4	
		p-value	0.4116	
		Corrected Hedges' g (95% CI)	-0.22 (-0.76, 0.32)	
Week 157	Change from Baseline	n (%)	23 (12.0%)	19 (10.3%)
		LS Mean (SE)	-2.7 (2.91)	5.5 (3.17)
		95% CI	-8.4, 3.0	-0.7, 11.8
		Difference from placebo		
		LS Mean (SE)	-8.2 (4.35)	
		95% CI	-16.8, 0.3	
		p-value	0.0590	
		Corrected Hedges' g (95% CI)	-0.58 (-1.20, 0.04)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	20 (10.4%)	15 (8.2%)
		LS Mean (SE)	-1.2 (3.07)	5.3 (3.51)
		95% CI	-7.2, 4.8	-1.6, 12.1
		Difference from placebo		
		LS Mean (SE)	-6.5 (4.67)	
		95% CI	-15.6, 2.7	
		p-value	0.1652	
		Corrected Hedges' g (95% CI)	-0.46 (-1.14, 0.22)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	8 (4.3%)
		LS Mean (SE)	1.2 (3.31)	4.2 (4.66)
		95% CI	-5.3, 7.7	-5.0, 13.3
		Difference from placebo		
		LS Mean (SE)	-3.0 (5.73)	
		95% CI	-14.2, 8.2	
		p-value	0.6025	
		Corrected Hedges' g (95% CI)	-0.21 (-1.06, 0.63)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	10 (5.4%)
		LS Mean (SE)	-1.8 (4.14)	-1.2 (4.28)
		95% CI	-10.0, 6.3	-9.6, 7.2
		Difference from placebo		
		LS Mean (SE)	-0.6 (5.91)	
		95% CI	-12.2, 11.0	
		p-value	0.9143	
		Corrected Hedges' g (95% CI)	-0.04 (-0.88, 0.80)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	6 (3.3%)
		LS Mean (SE)	-5.3 (4.55)	2.6 (5.43)
		95% CI	-14.2, 3.6	-8.1, 13.2
		Difference from placebo		
		LS Mean (SE)	-7.9 (7.07)	
		95% CI	-21.7, 6.0	
		p-value	0.2663	
		Corrected Hedges' g (95% CI)	-0.55 (-1.60, 0.50)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	-3.5 (9.45)	7.5 (9.29)
		95% CI	-22.0, 15.0	-10.7, 25.7
		Difference from placebo		
		LS Mean (SE)	-11.0 (12.74)	
		95% CI	-36.0, 13.9	
		p-value	0.3862	
		Corrected Hedges' g (95% CI)	-0.47 (-2.13, 1.19)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	170 (88.5%)	162 (88.0%)
		LS Mean (SE)	0.7 (0.91)	1.3 (0.95)
		95% CI	-1.1, 2.5	-0.6, 3.1
		Difference from placebo		
		LS Mean (SE)	-0.6 (1.32)	
		95% CI	-3.1, 2.0	
		p-value	0.6760	
		Corrected Hedges' g (95% CI)	-0.05 (-0.26, 0.17)	
Week 4	Change from Baseline	n (%)	163 (84.9%)	159 (86.4%)
		LS Mean (SE)	0.2 (1.20)	-0.1 (1.22)
		95% CI	-2.1, 2.6	-2.5, 2.3
		Difference from placebo		
		LS Mean (SE)	0.3 (1.71)	
		95% CI	-3.1, 3.6	
		p-value	0.8637	
		Corrected Hedges' g (95% CI)	0.02 (-0.20, 0.24)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	155 (80.7%)	146 (79.3%)
		LS Mean (SE)	-1.4 (1.21)	-0.4 (1.25)
		95% CI	-3.8, 1.0	-2.8, 2.1
		Difference from placebo		
		LS Mean (SE)	-1.0 (1.74)	
		95% CI	-4.5, 2.4	
		p-value	0.5530	
		Corrected Hedges' g (95% CI)	-0.07 (-0.29, 0.16)	
Week 10	Change from Baseline	n (%)	151 (78.6%)	137 (74.5%)
		LS Mean (SE)	-0.4 (1.22)	-0.2 (1.27)
		95% CI	-2.8, 2.0	-2.7, 2.3
		Difference from placebo		
		LS Mean (SE)	-0.2 (1.77)	
		95% CI	-3.7, 3.3	
		p-value	0.9087	
		Corrected Hedges' g (95% CI)	-0.01 (-0.24, 0.22)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	138 (71.9%)	132 (71.7%)
		LS Mean (SE)	-2.3 (1.26)	-0.9 (1.29)
		95% CI	-4.7, 0.2	-3.4, 1.6
		Difference from placebo		
		LS Mean (SE)	-1.4 (1.80)	
		95% CI	-4.9, 2.2	
		p-value	0.4473	
		Corrected Hedges' g (95% CI)	-0.09 (-0.33, 0.15)	
Week 16	Change from Baseline	n (%)	133 (69.3%)	126 (68.5%)
		LS Mean (SE)	-1.9 (1.27)	-0.7 (1.31)
		95% CI	-4.4, 0.6	-3.3, 1.8
		Difference from placebo		
		LS Mean (SE)	-1.2 (1.83)	
		95% CI	-4.8, 2.4	
		p-value	0.5220	
		Corrected Hedges' g (95% CI)	-0.08 (-0.32, 0.16)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	135 (70.3%)	126 (68.5%)
		LS Mean (SE)	-1.2 (1.27)	1.7 (1.31)
		95% CI	-3.7, 1.3	-0.9, 4.3
		Difference from placebo		
		LS Mean (SE)	-2.9 (1.83)	
		95% CI	-6.5, 0.7	
		p-value	0.1093	
		Corrected Hedges' g (95% CI)	-0.20 (-0.44, 0.05)	
Week 25	Change from Baseline	n (%)	122 (63.5%)	115 (62.5%)
		LS Mean (SE)	0.4 (1.31)	0.3 (1.35)
		95% CI	-2.2, 3.0	-2.3, 3.0
		Difference from placebo		
		LS Mean (SE)	0.0 (1.88)	
		95% CI	-3.7, 3.7	
		p-value	0.9820	
		Corrected Hedges' g (95% CI)	0.00 (-0.25, 0.26)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	114 (59.4%)	112 (60.9%)
		LS Mean (SE)	1.8 (1.35)	2.0 (1.37)
		95% CI	-0.8, 4.5	-0.7, 4.7
		Difference from placebo		
		LS Mean (SE)	-0.2 (1.92)	
		95% CI	-4.0, 3.6	
		p-value	0.9227	
		Corrected Hedges' g (95% CI)	-0.01 (-0.27, 0.25)	
Week 37	Change from Baseline	n (%)	102 (53.1%)	91 (49.5%)
		LS Mean (SE)	2.3 (1.40)	1.9 (1.46)
		95% CI	-0.4, 5.1	-1.0, 4.8
		Difference from placebo		
		LS Mean (SE)	0.5 (2.02)	
		95% CI	-3.5, 4.4	
		p-value	0.8205	
		Corrected Hedges' g (95% CI)	0.03 (-0.25, 0.32)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	93 (48.4%)	89 (48.4%)
		LS Mean (SE)	5.3 (1.45)	2.4 (1.48)
		95% CI	2.5, 8.1	-0.5, 5.3
		Difference from placebo		
		LS Mean (SE)	2.9 (2.07)	
		95% CI	-1.2, 6.9	
		p-value	0.1663	
		Corrected Hedges' g (95% CI)	0.20 (-0.09, 0.50)	
Week 49	Change from Baseline	n (%)	81 (42.2%)	68 (37.0%)
		LS Mean (SE)	0.3 (1.51)	1.5 (1.62)
		95% CI	-2.7, 3.3	-1.7, 4.7
		Difference from placebo		
		LS Mean (SE)	-1.2 (2.22)	
		95% CI	-5.6, 3.2	
		p-value	0.5896	
		Corrected Hedges' g (95% CI)	-0.09 (-0.41, 0.23)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	78 (40.6%)	68 (37.0%)
		LS Mean (SE)	2.1 (1.54)	0.5 (1.63)
		95% CI	-0.9, 5.1	-2.7, 3.7
		Difference from placebo		
		LS Mean (SE)	1.6 (2.24)	
		95% CI	-2.8, 6.0	
		p-value	0.4639	
		Corrected Hedges' g (95% CI)	0.12 (-0.20, 0.45)	
Week 61	Change from Baseline	n (%)	70 (36.5%)	56 (30.4%)
		LS Mean (SE)	-0.0 (1.60)	2.8 (1.75)
		95% CI	-3.2, 3.1	-0.7, 6.2
		Difference from placebo		
		LS Mean (SE)	-2.8 (2.38)	
		95% CI	-7.5, 1.9	
		p-value	0.2403	
		Corrected Hedges' g (95% CI)	-0.21 (-0.56, 0.14)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	70 (36.5%)	63 (34.2%)
		LS Mean (SE)	-0.9 (1.60)	-0.3 (1.68)
		95% CI	-4.0, 2.3	-3.6, 3.0
		Difference from placebo		
		LS Mean (SE)	-0.6 (2.32)	
		95% CI	-5.1, 4.0	
		p-value	0.7979	
		Corrected Hedges' g (95% CI)	-0.04 (-0.38, 0.30)	
Week 73	Change from Baseline	n (%)	66 (34.4%)	54 (29.3%)
		LS Mean (SE)	2.3 (1.65)	1.3 (1.78)
		95% CI	-0.9, 5.5	-2.2, 4.8
		Difference from placebo		
		LS Mean (SE)	1.0 (2.44)	
		95% CI	-3.8, 5.8	
		p-value	0.6746	
		Corrected Hedges' g (95% CI)	0.08 (-0.28, 0.44)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	56 (29.2%)	48 (26.1%)
		LS Mean (SE)	-0.5 (1.73)	-0.8 (1.86)
		95% CI	-3.9, 2.9	-4.5, 2.8
		Difference from placebo		
		LS Mean (SE)	0.4 (2.55)	
		95% CI	-4.6, 5.4	
		p-value	0.8848	
		Corrected Hedges' g (95% CI)	0.03 (-0.36, 0.41)	
Week 85	Change from Baseline	n (%)	60 (31.3%)	53 (28.8%)
		LS Mean (SE)	0.4 (1.71)	-2.0 (1.80)
		95% CI	-3.0, 3.7	-5.5, 1.5
		Difference from placebo		
		LS Mean (SE)	2.4 (2.48)	
		95% CI	-2.5, 7.3	
		p-value	0.3362	
		Corrected Hedges' g (95% CI)	0.18 (-0.19, 0.55)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	47 (24.5%)	44 (23.9%)
		LS Mean (SE)	2.1 (1.88)	0.1 (1.92)
		95% CI	-1.6, 5.8	-3.7, 3.8
		Difference from placebo		
		LS Mean (SE)	2.1 (2.71)	
		95% CI	-3.3, 7.4	
		p-value	0.4467	
		Corrected Hedges' g (95% CI)	0.16 (-0.25, 0.57)	
Week 97	Change from Baseline	n (%)	56 (29.2%)	49 (26.6%)
		LS Mean (SE)	1.1 (1.75)	1.1 (1.86)
		95% CI	-2.3, 4.5	-2.5, 4.7
		Difference from placebo		
		LS Mean (SE)	0.0 (2.55)	
		95% CI	-5.0, 5.0	
		p-value	0.9930	
		Corrected Hedges' g (95% CI)	0.00 (-0.38, 0.39)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	50 (26.0%)	38 (20.7%)
		LS Mean (SE)	-1.2 (1.84)	0.6 (2.05)
		95% CI	-4.8, 2.4	-3.4, 4.6
		Difference from placebo		
		LS Mean (SE)	-1.8 (2.78)	
		95% CI	-7.2, 3.7	
		p-value	0.5230	
		Corrected Hedges' g (95% CI)	-0.14 (-0.56, 0.29)	
Week 109	Change from Baseline	n (%)	45 (23.4%)	43 (23.4%)
		LS Mean (SE)	-1.4 (1.90)	1.8 (1.95)
		95% CI	-5.1, 2.3	-2.0, 5.7
		Difference from placebo		
		LS Mean (SE)	-3.3 (2.72)	
		95% CI	-8.6, 2.1	
		p-value	0.2312	
		Corrected Hedges' g (95% CI)	-0.25 (-0.67, 0.17)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	47 (24.5%)	38 (20.7%)
		LS Mean (SE)	0.4 (1.88)	0.5 (2.05)
		95% CI	-3.3, 4.1	-3.5, 4.5
		Difference from placebo		
		LS Mean (SE)	-0.1 (2.80)	
		95% CI	-5.6, 5.3	
		p-value	0.9599	
		Corrected Hedges' g (95% CI)	-0.01 (-0.44, 0.42)	
Week 121	Change from Baseline	n (%)	43 (22.4%)	45 (24.5%)
		LS Mean (SE)	1.5 (1.94)	3.1 (1.92)
		95% CI	-2.3, 5.3	-0.7, 6.9
		Difference from placebo		
		LS Mean (SE)	-1.6 (2.73)	
		95% CI	-7.0, 3.7	
		p-value	0.5466	
		Corrected Hedges' g (95% CI)	-0.13 (-0.55, 0.29)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	41 (21.4%)	37 (20.1%)
		LS Mean (SE)	0.8 (1.97)	0.9 (2.08)
		95% CI	-3.0, 4.7	-3.2, 4.9
		Difference from placebo		
		LS Mean (SE)	-0.0 (2.88)	
		95% CI	-5.7, 5.6	
		p-value	0.9934	
		Corrected Hedges' g (95% CI)	-0.00 (-0.45, 0.44)	
Week 133	Change from Baseline	n (%)	41 (21.4%)	37 (20.1%)
		LS Mean (SE)	3.8 (1.99)	1.4 (2.08)
		95% CI	-0.1, 7.7	-2.7, 5.5
		Difference from placebo		
		LS Mean (SE)	2.4 (2.90)	
		95% CI	-3.2, 8.1	
		p-value	0.3992	
		Corrected Hedges' g (95% CI)	0.19 (-0.26, 0.64)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	42 (21.9%)	31 (16.8%)
		LS Mean (SE)	-0.1 (1.96)	3.3 (2.26)
		95% CI	-3.9, 3.7	-1.1, 7.7
		Difference from placebo		
		LS Mean (SE)	-3.4 (2.99)	
		95% CI	-9.3, 2.5	
		p-value	0.2544	
		Corrected Hedges' g (95% CI)	-0.27 (-0.73, 0.20)	
Week 145	Change from Baseline	n (%)	33 (17.2%)	27 (14.7%)
		LS Mean (SE)	-0.7 (2.18)	1.6 (2.37)
		95% CI	-5.0, 3.6	-3.1, 6.2
		Difference from placebo		
		LS Mean (SE)	-2.3 (3.21)	
		95% CI	-8.6, 4.0	
		p-value	0.4705	
		Corrected Hedges' g (95% CI)	-0.18 (-0.69, 0.33)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	32 (16.7%)	23 (12.5%)
		LS Mean (SE)	3.1 (2.22)	2.6 (2.55)
		95% CI	-1.3, 7.4	-2.4, 7.6
		Difference from placebo		
		LS Mean (SE)	0.4 (3.41)	
		95% CI	-6.2, 7.1	
		p-value	0.8992	
		Corrected Hedges' g (95% CI)	0.03 (-0.50, 0.57)	
Week 157	Change from Baseline	n (%)	22 (11.5%)	19 (10.3%)
		LS Mean (SE)	-1.1 (2.58)	1.1 (2.78)
		95% CI	-6.2, 3.9	-4.3, 6.6
		Difference from placebo		
		LS Mean (SE)	-2.3 (3.80)	
		95% CI	-9.7, 5.2	
		p-value	0.5524	
		Corrected Hedges' g (95% CI)	-0.18 (-0.80, 0.43)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	20 (10.4%)	15 (8.2%)
		LS Mean (SE)	0.8 (2.71)	3.2 (3.11)
		95% CI	-4.5, 6.2	-2.9, 9.3
		Difference from placebo		
		LS Mean (SE)	-2.4 (4.14)	
		95% CI	-10.5, 5.7	
		p-value	0.5667	
		Corrected Hedges' g (95% CI)	-0.19 (-0.86, 0.48)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	8 (4.3%)
		LS Mean (SE)	5.1 (3.01)	5.2 (4.46)
		95% CI	-0.8, 11.0	-3.6, 13.9
		Difference from placebo		
		LS Mean (SE)	-0.1 (5.13)	
		95% CI	-10.1, 10.0	
		p-value	0.9919	
		Corrected Hedges' g (95% CI)	-0.00 (-0.84, 0.84)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	10 (5.4%)
		LS Mean (SE)	2.0 (3.50)	4.9 (3.79)
		95% CI	-4.9, 8.8	-2.6, 12.3
		Difference from placebo		
		LS Mean (SE)	-2.9 (5.17)	
		95% CI	-13.1, 7.2	
		p-value	0.5726	
		Corrected Hedges' g (95% CI)	-0.23 (-1.07, 0.61)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	29 (15.1%)	35 (19.0%)
		LS Mean (SE)	-0.9 (4.17)	-5.4 (4.21)
		95% CI	-9.3, 7.4	-13.7, 3.0
		Difference from placebo		
		LS Mean (SE)	4.4 (5.94)	
		95% CI	-7.4, 16.3	
		p-value	0.4579	
		Corrected Hedges' g (95% CI)	0.18 (-0.31, 0.68)	
Week 4	Change from Baseline	n (%)	19 (9.9%)	24 (13.0%)
		LS Mean (SE)	-1.6 (5.16)	-1.0 (4.69)
		95% CI	-11.8, 8.6	-10.3, 8.3
		Difference from placebo		
		LS Mean (SE)	-0.6 (6.94)	
		95% CI	-14.3, 13.1	
		p-value	0.9298	
		Corrected Hedges' g (95% CI)	-0.03 (-0.63, 0.58)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	19 (9.9%)	23 (12.5%)
		LS Mean (SE)	2.3 (5.13)	-5.8 (4.71)
		95% CI	-7.9, 12.4	-15.1, 3.5
		Difference from placebo		
		LS Mean (SE)	8.1 (6.96)	
		95% CI	-5.7, 21.8	
		p-value	0.2474	
		Corrected Hedges' g (95% CI)	0.35 (-0.26, 0.96)	
Week 10	Change from Baseline	n (%)	16 (8.3%)	20 (10.9%)
		LS Mean (SE)	1.4 (5.36)	-1.6 (4.87)
		95% CI	-9.2, 12.0	-11.2, 8.0
		Difference from placebo		
		LS Mean (SE)	3.0 (7.24)	
		95% CI	-11.3, 17.3	
		p-value	0.6800	
		Corrected Hedges' g (95% CI)	0.14 (-0.52, 0.79)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	15 (7.8%)	22 (12.0%)
		LS Mean (SE)	-0.8 (5.49)	-6.8 (4.82)
		95% CI	-11.7, 10.0	-16.3, 2.7
		Difference from placebo		
		LS Mean (SE)	6.0 (7.30)	
		95% CI	-8.4, 20.4	
		p-value	0.4145	
		Corrected Hedges' g (95% CI)	0.26 (-0.39, 0.92)	
Week 16	Change from Baseline	n (%)	13 (6.8%)	22 (12.0%)
		LS Mean (SE)	-2.5 (5.70)	-11.8 (4.83)
		95% CI	-13.7, 8.8	-21.3, -2.2
		Difference from placebo		
		LS Mean (SE)	9.3 (7.45)	
		95% CI	-5.4, 24.0	
		p-value	0.2122	
		Corrected Hedges' g (95% CI)	0.42 (-0.28, 1.11)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	16 (8.3%)	17 (9.2%)
		LS Mean (SE)	-8.6 (5.36)	-5.9 (5.14)
		95% CI	-19.2, 2.0	-16.1, 4.2
		Difference from placebo		
		LS Mean (SE)	-2.7 (7.43)	
		95% CI	-17.4, 12.0	
		p-value	0.7180	
		Corrected Hedges' g (95% CI)	-0.12 (-0.81, 0.56)	
Week 25	Change from Baseline	n (%)	16 (8.3%)	15 (8.2%)
		LS Mean (SE)	-0.8 (5.33)	-0.7 (5.37)
		95% CI	-11.4, 9.7	-11.3, 9.9
		Difference from placebo		
		LS Mean (SE)	-0.2 (7.57)	
		95% CI	-15.1, 14.8	
		p-value	0.9825	
		Corrected Hedges' g (95% CI)	-0.01 (-0.71, 0.70)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	20 (10.4%)	13 (7.1%)
		LS Mean (SE)	2.0 (5.08)	-9.0 (5.66)
		95% CI	-8.1, 12.0	-20.1, 2.2
		Difference from placebo		
		LS Mean (SE)	10.9 (7.60)	
		95% CI	-4.1, 25.9	
		p-value	0.1516	
		Corrected Hedges' g (95% CI)	0.49 (-0.22, 1.20)	
Week 37	Change from Baseline	n (%)	13 (6.8%)	11 (6.0%)
		LS Mean (SE)	3.2 (5.58)	-9.9 (5.92)
		95% CI	-7.8, 14.2	-21.6, 1.7
		Difference from placebo		
		LS Mean (SE)	13.1 (8.13)	
		95% CI	-2.9, 29.2	
		p-value	0.1078	
		Corrected Hedges' g (95% CI)	0.64 (-0.19, 1.46)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	17 (8.9%)	9 (4.9%)
		LS Mean (SE)	-3.1 (5.35)	-11.7 (6.30)
		95% CI	-13.7, 7.4	-24.2, 0.7
		Difference from placebo		
		LS Mean (SE)	8.6 (8.27)	
		95% CI	-7.7, 24.9	
		p-value	0.2994	
		Corrected Hedges' g (95% CI)	0.40 (-0.42, 1.21)	
Week 49	Change from Baseline	n (%)	11 (5.7%)	8 (4.3%)
		LS Mean (SE)	-5.7 (5.95)	-10.2 (6.67)
		95% CI	-17.4, 6.1	-23.3, 2.9
		Difference from placebo		
		LS Mean (SE)	4.5 (8.96)	
		95% CI	-13.1, 22.2	
		p-value	0.6150	
		Corrected Hedges' g (95% CI)	0.22 (-0.69, 1.14)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	11 (5.7%)	6 (3.3%)
		LS Mean (SE)	1.4 (6.03)	-11.1 (7.30)
		95% CI	-10.4, 13.3	-25.5, 3.3
		Difference from placebo		
		LS Mean (SE)	12.5 (9.41)	
		95% CI	-6.0, 31.1	
		p-value	0.1836	
		Corrected Hedges' g (95% CI)	0.62 (-0.40, 1.63)	
Week 61	Change from Baseline	n (%)	8 (4.2%)	6 (3.3%)
		LS Mean (SE)	0.8 (6.64)	-8.5 (7.32)
		95% CI	-12.3, 13.9	-22.9, 5.9
		Difference from placebo		
		LS Mean (SE)	9.3 (9.85)	
		95% CI	-10.1, 28.7	
		p-value	0.3447	
		Corrected Hedges' g (95% CI)	0.47 (-0.60, 1.55)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	6 (3.1%)	5 (2.7%)
		LS Mean (SE)	-8.9 (7.48)	-5.8 (8.94)
		95% CI	-23.6, 5.8	-23.4, 11.7
		Difference from placebo		
		LS Mean (SE)	-3.0 (12.32)	
		95% CI	-27.3, 21.2	
		p-value	0.8054	
		Corrected Hedges' g (95% CI)	-0.15 (-1.33, 1.04)	
Week 73	Change from Baseline	n (%)	7 (3.6%)	3 (1.6%)
		LS Mean (SE)	-1.6 (6.95)	-8.6 (9.59)
		95% CI	-15.3, 12.1	-27.4, 10.3
		Difference from placebo		
		LS Mean (SE)	7.0 (11.83)	
		95% CI	-16.3, 30.3	
		p-value	0.5542	
		Corrected Hedges' g (95% CI)	0.35 (-1.01, 1.71)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	6 (3.1%)	3 (1.6%)
		LS Mean (SE)	-7.2 (7.44)	-6.8 (10.18)
		95% CI	-21.9, 7.4	-26.8, 13.2
		Difference from placebo		
		LS Mean (SE)	-0.4 (12.94)	
		95% CI	-25.9, 25.0	
		p-value	0.9731	
		Corrected Hedges' g (95% CI)	-0.02 (-1.41, 1.36)	
Week 85	Change from Baseline	n (%)	3 (1.6%)	5 (2.7%)
		LS Mean (SE)	2.3 (9.65)	-11.7 (8.28)
		95% CI	-16.7, 21.3	-28.0, 4.6
		Difference from placebo		
		LS Mean (SE)	14.0 (12.80)	
		95% CI	-11.1, 39.2	
		p-value	0.2737	
		Corrected Hedges' g (95% CI)	0.68 (-0.79, 2.15)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	4 (2.1%)	2 (1.1%)
		LS Mean (SE)	11.7 (8.63)	-7.1 (11.73)
		95% CI	-5.3, 28.7	-30.2, 15.9
		Difference from placebo		
		LS Mean (SE)	18.8 (14.55)	
		95% CI	-9.8, 47.5	
		p-value	0.1961	
		Corrected Hedges' g (95% CI)	0.88 (-0.89, 2.65)	
Week 97	Change from Baseline	n (%)	5 (2.6%)	3 (1.6%)
		LS Mean (SE)	-10.4 (8.93)	6.9 (10.48)
		95% CI	-28.0, 7.2	-13.7, 27.5
		Difference from placebo		
		LS Mean (SE)	-17.3 (12.55)	
		95% CI	-42.0, 7.4	
		p-value	0.1689	
		Corrected Hedges' g (95% CI)	-0.78 (-2.26, 0.70)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	6 (3.1%)	2 (1.1%)
		LS Mean (SE)	-3.4 (8.04)	-4.6 (11.74)
		95% CI	-19.2, 12.4	-27.6, 18.5
		Difference from placebo		
		LS Mean (SE)	1.2 (14.34)	
		95% CI	-27.0, 29.4	
		p-value	0.9342	
		Corrected Hedges' g (95% CI)	0.05 (-1.55, 1.65)	
Week 121	Change from Baseline	n (%)	3 (1.6%)	4 (2.2%)
		LS Mean (SE)	15.2 (11.12)	7.8 (12.68)
		95% CI	-6.7, 37.0	-17.2, 32.7
		Difference from placebo		
		LS Mean (SE)	7.4 (13.70)	
		95% CI	-19.6, 34.3	
		p-value	0.5907	
		Corrected Hedges' g (95% CI)	0.27 (-1.23, 1.77)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	4 (2.1%)	3 (1.6%)
		LS Mean (SE)	-13.9 (9.23)	-30.4 (12.74)
		95% CI	-32.0, 4.3	-55.5, -5.4
		Difference from placebo		
		LS Mean (SE)	16.5 (17.25)	
		95% CI	-17.4, 50.5	
		p-value	0.3384	
		Corrected Hedges' g (95% CI)	0.70 (-0.84, 2.24)	
Week 133	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	2.0 (8.11)	12.7 (13.76)
		95% CI	-14.0, 18.0	-14.4, 39.8
		Difference from placebo		
		LS Mean (SE)	-10.7 (15.98)	
		95% CI	-42.2, 20.8	
		p-value	0.5033	
		Corrected Hedges' g (95% CI)	-0.49 (-2.15, 1.17)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 145	Change from Baseline	n (%)	4 (2.1%)	2 (1.1%)
		LS Mean (SE)	4.0 (8.78)	13.1 (14.16)
		95% CI	-13.3, 21.3	-14.8, 41.0
		Difference from placebo		
		LS Mean (SE)	-9.0 (16.36)	
		95% CI	-41.3, 23.2	
		p-value	0.5808	
		Corrected Hedges' g (95% CI)	-0.40 (-2.11, 1.31)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	172 (93.5%)
		LS Mean (SE)	6.3 (1.18)	5.0 (1.28)
		95% CI	3.9, 8.6	2.5, 7.5
		Difference from placebo		
		LS Mean (SE)	1.3 (1.75)	
		95% CI	-2.2, 4.7	
		p-value	0.4669	
		Corrected Hedges' g (95% CI)	0.08 (-0.13, 0.29)	
Week 4	Change from Baseline	n (%)	177 (92.2%)	170 (92.4%)
		LS Mean (SE)	2.3 (1.52)	2.2 (1.55)
		95% CI	-0.7, 5.3	-0.9, 5.2
		Difference from placebo		
		LS Mean (SE)	0.1 (2.18)	
		95% CI	-4.2, 4.4	
		p-value	0.9659	
		Corrected Hedges' g (95% CI)	0.00 (-0.21, 0.22)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	169 (88.0%)	161 (87.5%)
		LS Mean (SE)	5.7 (1.54)	0.6 (1.58)
		95% CI	2.6, 8.7	-2.5, 3.7
		Difference from placebo		
		LS Mean (SE)	5.1 (2.21)	
		95% CI	0.7, 9.4	
		p-value	0.0216	
		Corrected Hedges' g (95% CI)	0.25 (0.04, 0.47)	
Week 10	Change from Baseline	n (%)	166 (86.5%)	152 (82.6%)
		LS Mean (SE)	6.5 (1.55)	3.1 (1.60)
		95% CI	3.5, 9.6	-0.1, 6.2
		Difference from placebo		
		LS Mean (SE)	3.4 (2.23)	
		95% CI	-0.9, 7.8	
		p-value	0.1232	
		Corrected Hedges' g (95% CI)	0.17 (-0.05, 0.39)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	144 (78.3%)
		LS Mean (SE)	6.0 (1.57)	3.8 (1.63)
		95% CI	2.9, 9.0	0.6, 7.0
		Difference from placebo		
		LS Mean (SE)	2.2 (2.26)	
		95% CI	-2.3, 6.6	
		p-value	0.3368	
		Corrected Hedges' g (95% CI)	0.11 (-0.12, 0.34)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	146 (79.3%)
		LS Mean (SE)	9.3 (1.58)	7.6 (1.63)
		95% CI	6.2, 12.4	4.4, 10.7
		Difference from placebo		
		LS Mean (SE)	1.7 (2.28)	
		95% CI	-2.8, 6.2	
		p-value	0.4528	
		Corrected Hedges' g (95% CI)	0.09 (-0.14, 0.31)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	146 (79.3%)
		LS Mean (SE)	10.2 (1.59)	6.6 (1.63)
		95% CI	7.0, 13.3	3.4, 9.8
		Difference from placebo		
		LS Mean (SE)	3.5 (2.28)	
		95% CI	-0.9, 8.0	
		p-value	0.1211	
		Corrected Hedges' g (95% CI)	0.18 (-0.05, 0.41)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	130 (70.7%)
		LS Mean (SE)	6.6 (1.64)	4.6 (1.69)
		95% CI	3.4, 9.8	1.3, 7.9
		Difference from placebo		
		LS Mean (SE)	2.0 (2.35)	
		95% CI	-2.6, 6.6	
		p-value	0.4031	
		Corrected Hedges' g (95% CI)	0.10 (-0.14, 0.34)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	127 (66.1%)	130 (70.7%)
		LS Mean (SE)	6.6 (1.69)	2.7 (1.70)
		95% CI	3.3, 9.9	-0.6, 6.1
		Difference from placebo		
		LS Mean (SE)	3.9 (2.40)	
		95% CI	-0.8, 8.6	
		p-value	0.1044	
		Corrected Hedges' g (95% CI)	0.20 (-0.04, 0.45)	
Week 37	Change from Baseline	n (%)	113 (58.9%)	104 (56.5%)
		LS Mean (SE)	7.8 (1.75)	3.9 (1.81)
		95% CI	4.4, 11.3	0.4, 7.5
		Difference from placebo		
		LS Mean (SE)	3.9 (2.53)	
		95% CI	-1.1, 8.8	
		p-value	0.1240	
		Corrected Hedges' g (95% CI)	0.21 (-0.06, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	106 (55.2%)	104 (56.5%)
		LS Mean (SE)	5.5 (1.79)	1.7 (1.84)
		95% CI	2.0, 9.1	-1.9, 5.3
		Difference from placebo		
		LS Mean (SE)	3.8 (2.57)	
		95% CI	-1.2, 8.9	
		p-value	0.1361	
		Corrected Hedges' g (95% CI)	0.21 (-0.07, 0.48)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	81 (44.0%)
		LS Mean (SE)	6.4 (1.88)	5.1 (1.97)
		95% CI	2.8, 10.1	1.2, 8.9
		Difference from placebo		
		LS Mean (SE)	1.4 (2.72)	
		95% CI	-4.0, 6.7	
		p-value	0.6125	
		Corrected Hedges' g (95% CI)	0.08 (-0.22, 0.38)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	90 (46.9%)	82 (44.6%)
		LS Mean (SE)	7.4 (1.90)	5.5 (1.98)
		95% CI	3.7, 11.1	1.6, 9.4
		Difference from placebo		
		LS Mean (SE)	1.9 (2.75)	
		95% CI	-3.5, 7.3	
		p-value	0.4963	
		Corrected Hedges' g (95% CI)	0.10 (-0.20, 0.40)	
Week 61	Change from Baseline	n (%)	79 (41.1%)	64 (34.8%)
		LS Mean (SE)	6.9 (1.99)	4.3 (2.15)
		95% CI	3.0, 10.8	0.1, 8.5
		Difference from placebo		
		LS Mean (SE)	2.6 (2.94)	
		95% CI	-3.1, 8.4	
		p-value	0.3736	
		Corrected Hedges' g (95% CI)	0.15 (-0.18, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	70 (38.0%)
		LS Mean (SE)	5.1 (1.98)	3.6 (2.10)
		95% CI	1.2, 8.9	-0.5, 7.7
		Difference from placebo		
		LS Mean (SE)	1.5 (2.89)	
		95% CI	-4.2, 7.1	
		p-value	0.6076	
		Corrected Hedges' g (95% CI)	0.08 (-0.24, 0.40)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	61 (33.2%)
		LS Mean (SE)	7.3 (2.03)	2.9 (2.22)
		95% CI	3.3, 11.2	-1.4, 7.3
		Difference from placebo		
		LS Mean (SE)	4.3 (3.03)	
		95% CI	-1.6, 10.3	
		p-value	0.1530	
		Corrected Hedges' g (95% CI)	0.25 (-0.09, 0.59)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	65 (33.9%)	56 (30.4%)
		LS Mean (SE)	7.4 (2.13)	6.1 (2.28)
		95% CI	3.2, 11.5	1.6, 10.5
		Difference from placebo		
		LS Mean (SE)	1.3 (3.13)	
		95% CI	-4.9, 7.4	
		p-value	0.6812	
		Corrected Hedges' g (95% CI)	0.07 (-0.28, 0.43)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	6.1 (2.13)	5.9 (2.27)
		95% CI	1.9, 10.2	1.5, 10.4
		Difference from placebo		
		LS Mean (SE)	0.1 (3.13)	
		95% CI	-6.0, 6.3	
		p-value	0.9672	
		Corrected Hedges' g (95% CI)	0.01 (-0.34, 0.36)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	54 (28.1%)	48 (26.1%)
		LS Mean (SE)	5.1 (2.28)	6.8 (2.44)
		95% CI	0.6, 9.5	2.1, 11.6
		Difference from placebo		
		LS Mean (SE)	-1.8 (3.35)	
		95% CI	-8.3, 4.8	
		p-value	0.6008	
		Corrected Hedges' g (95% CI)	-0.10 (-0.49, 0.29)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	7.4 (2.17)	3.7 (2.38)
		95% CI	3.1, 11.6	-0.9, 8.4
		Difference from placebo		
		LS Mean (SE)	3.6 (3.23)	
		95% CI	-2.7, 10.0	
		p-value	0.2615	
		Corrected Hedges' g (95% CI)	0.21 (-0.16, 0.58)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	42 (22.8%)
		LS Mean (SE)	4.3 (2.31)	3.9 (2.58)
		95% CI	-0.2, 8.9	-1.1, 9.0
		Difference from placebo		
		LS Mean (SE)	0.4 (3.52)	
		95% CI	-6.5, 7.3	
		p-value	0.9101	
		Corrected Hedges' g (95% CI)	0.02 (-0.38, 0.43)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	5.0 (2.35)	3.7 (2.40)
		95% CI	0.4, 9.7	-1.0, 8.4
		Difference from placebo		
		LS Mean (SE)	1.3 (3.37)	
		95% CI	-5.3, 7.9	
		p-value	0.6951	
		Corrected Hedges' g (95% CI)	0.08 (-0.31, 0.47)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	41 (22.3%)
		LS Mean (SE)	8.0 (2.42)	8.9 (2.61)
		95% CI	3.3, 12.8	3.8, 14.0
		Difference from placebo		
		LS Mean (SE)	-0.9 (3.61)	
		95% CI	-7.9, 6.2	
		p-value	0.8110	
		Corrected Hedges' g (95% CI)	-0.05 (-0.47, 0.36)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	49 (26.6%)
		LS Mean (SE)	6.4 (2.39)	4.8 (2.46)
		95% CI	1.7, 11.1	0.0, 9.6
		Difference from placebo		
		LS Mean (SE)	1.6 (3.45)	
		95% CI	-5.2, 8.4	
		p-value	0.6454	
		Corrected Hedges' g (95% CI)	0.09 (-0.30, 0.49)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	41 (22.3%)
		LS Mean (SE)	6.9 (2.51)	7.0 (2.60)
		95% CI	2.0, 11.8	1.9, 12.1
		Difference from placebo		
		LS Mean (SE)	-0.1 (3.64)	
		95% CI	-7.2, 7.0	
		p-value	0.9777	
		Corrected Hedges' g (95% CI)	-0.01 (-0.43, 0.42)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	42 (22.8%)
		LS Mean (SE)	5.4 (2.47)	9.2 (2.58)
		95% CI	0.5, 10.2	4.2, 14.3
		Difference from placebo		
		LS Mean (SE)	-3.9 (3.58)	
		95% CI	-10.9, 3.1	
		p-value	0.2795	
		Corrected Hedges' g (95% CI)	-0.23 (-0.65, 0.19)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	2.5 (2.51)	10.4 (2.78)
		95% CI	-2.4, 7.4	5.0, 15.8
		Difference from placebo		
		LS Mean (SE)	-7.9 (3.78)	
		95% CI	-15.3, -0.5	
		p-value	0.0369	
		Corrected Hedges' g (95% CI)	-0.47 (-0.91, -0.02)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	30 (16.3%)
		LS Mean (SE)	2.2 (2.69)	3.1 (2.99)
		95% CI	-3.1, 7.5	-2.7, 9.0
		Difference from placebo		
		LS Mean (SE)	-0.9 (4.04)	
		95% CI	-8.9, 7.0	
		p-value	0.8164	
		Corrected Hedges' g (95% CI)	-0.06 (-0.54, 0.42)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	25 (13.6%)
		LS Mean (SE)	6.1 (2.79)	10.7 (3.23)
		95% CI	0.6, 11.5	4.3, 17.0
		Difference from placebo		
		LS Mean (SE)	-4.6 (4.29)	
		95% CI	-13.0, 3.8	
		p-value	0.2814	
		Corrected Hedges' g (95% CI)	-0.28 (-0.79, 0.24)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	19 (10.3%)
		LS Mean (SE)	7.5 (3.13)	8.0 (3.71)
		95% CI	1.3, 13.6	0.7, 15.3
		Difference from placebo		
		LS Mean (SE)	-0.5 (4.85)	
		95% CI	-10.0, 9.0	
		p-value	0.9135	
		Corrected Hedges' g (95% CI)	-0.03 (-0.62, 0.56)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	6.1 (3.45)	7.9 (3.92)
		95% CI	-0.7, 12.9	0.2, 15.6
		Difference from placebo		
		LS Mean (SE)	-1.8 (5.25)	
		95% CI	-12.1, 8.5	
		p-value	0.7328	
		Corrected Hedges' g (95% CI)	-0.11 (-0.75, 0.53)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	10 (5.4%)
		LS Mean (SE)	7.6 (4.00)	5.8 (4.89)
		95% CI	-0.2, 15.5	-3.8, 15.4
		Difference from placebo		
		LS Mean (SE)	1.9 (6.46)	
		95% CI	-10.8, 14.5	
		p-value	0.7717	
		Corrected Hedges' g (95% CI)	0.11 (-0.67, 0.89)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	9.7 (4.61)	4.5 (4.89)
		95% CI	0.7, 18.8	-5.1, 14.0
		Difference from placebo		
		LS Mean (SE)	5.3 (6.83)	
		95% CI	-8.1, 18.7	
		p-value	0.4390	
		Corrected Hedges' g (95% CI)	0.32 (-0.51, 1.14)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	7 (3.8%)
		LS Mean (SE)	5.3 (5.64)	1.2 (5.91)
		95% CI	-5.8, 16.3	-10.4, 12.8
		Difference from placebo		
		LS Mean (SE)	4.1 (8.34)	
		95% CI	-12.2, 20.5	
		p-value	0.6219	
		Corrected Hedges' g (95% CI)	0.24 (-0.75, 1.23)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	4.4 (7.33)	-0.2 (11.25)
		95% CI	-9.9, 18.8	-22.3, 21.8
		Difference from placebo		
		LS Mean (SE)	4.7 (14.02)	
		95% CI	-22.8, 32.2	
		p-value	0.7390	
		Corrected Hedges' g (95% CI)	0.24 (-1.40, 1.89)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	180 (93.8%)	172 (93.5%)
		LS Mean (SE)	-0.3 (0.93)	-0.7 (1.01)
		95% CI	-2.2, 1.5	-2.7, 1.3
		Difference from placebo		
		LS Mean (SE)	0.4 (1.38)	
		95% CI	-2.3, 3.1	
		p-value	0.7903	
		Corrected Hedges' g (95% CI)	0.03 (-0.18, 0.24)	
Week 4	Change from Baseline	n (%)	176 (91.7%)	169 (91.8%)
		LS Mean (SE)	1.7 (1.18)	0.3 (1.20)
		95% CI	-0.7, 4.0	-2.0, 2.7
		Difference from placebo		
		LS Mean (SE)	1.3 (1.69)	
		95% CI	-2.0, 4.7	
		p-value	0.4278	
		Corrected Hedges' g (95% CI)	0.09 (-0.13, 0.30)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	168 (87.5%)	161 (87.5%)
		LS Mean (SE)	1.8 (1.19)	0.6 (1.22)
		95% CI	-0.5, 4.2	-1.8, 3.0
		Difference from placebo		
		LS Mean (SE)	1.2 (1.70)	
		95% CI	-2.1, 4.6	
		p-value	0.4634	
		Corrected Hedges' g (95% CI)	0.08 (-0.14, 0.30)	
Week 10	Change from Baseline	n (%)	164 (85.4%)	152 (82.6%)
		LS Mean (SE)	3.3 (1.20)	1.2 (1.24)
		95% CI	0.9, 5.6	-1.2, 3.6
		Difference from placebo		
		LS Mean (SE)	2.1 (1.72)	
		95% CI	-1.3, 5.4	
		p-value	0.2345	
		Corrected Hedges' g (95% CI)	0.13 (-0.09, 0.35)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	156 (81.3%)	144 (78.3%)
		LS Mean (SE)	1.5 (1.21)	2.0 (1.25)
		95% CI	-0.9, 3.9	-0.5, 4.4
		Difference from placebo		
		LS Mean (SE)	-0.4 (1.75)	
		95% CI	-3.9, 3.0	
		p-value	0.7973	
		Corrected Hedges' g (95% CI)	-0.03 (-0.26, 0.20)	
Week 16	Change from Baseline	n (%)	151 (78.6%)	146 (79.3%)
		LS Mean (SE)	1.5 (1.23)	0.2 (1.25)
		95% CI	-0.9, 3.9	-2.2, 2.7
		Difference from placebo		
		LS Mean (SE)	1.3 (1.75)	
		95% CI	-2.2, 4.7	
		p-value	0.4743	
		Corrected Hedges' g (95% CI)	0.08 (-0.14, 0.31)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	152 (79.2%)	146 (79.3%)
		LS Mean (SE)	1.9 (1.23)	-1.4 (1.26)
		95% CI	-0.5, 4.3	-3.8, 1.1
		Difference from placebo		
		LS Mean (SE)	3.3 (1.76)	
		95% CI	-0.2, 6.7	
		p-value	0.0643	
		Corrected Hedges' g (95% CI)	0.21 (-0.01, 0.44)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	130 (70.7%)
		LS Mean (SE)	-1.1 (1.26)	-1.3 (1.30)
		95% CI	-3.5, 1.4	-3.9, 1.2
		Difference from placebo		
		LS Mean (SE)	0.3 (1.81)	
		95% CI	-3.3, 3.8	
		p-value	0.8884	
		Corrected Hedges' g (95% CI)	0.02 (-0.22, 0.26)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	126 (65.6%)	129 (70.1%)
		LS Mean (SE)	-2.1 (1.30)	-2.4 (1.31)
		95% CI	-4.7, 0.4	-5.0, 0.2
		Difference from placebo		
		LS Mean (SE)	0.3 (1.85)	
		95% CI	-3.3, 3.9	
		p-value	0.8755	
		Corrected Hedges' g (95% CI)	0.02 (-0.23, 0.27)	
Week 37	Change from Baseline	n (%)	113 (58.9%)	105 (57.1%)
		LS Mean (SE)	-3.1 (1.34)	-1.7 (1.39)
		95% CI	-5.8, -0.5	-4.4, 1.0
		Difference from placebo		
		LS Mean (SE)	-1.4 (1.93)	
		95% CI	-5.2, 2.4	
		p-value	0.4663	
		Corrected Hedges' g (95% CI)	-0.10 (-0.36, 0.17)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	106 (55.2%)	104 (56.5%)
		LS Mean (SE)	-1.8 (1.38)	-1.1 (1.41)
		95% CI	-4.5, 0.9	-3.8, 1.7
		Difference from placebo		
		LS Mean (SE)	-0.7 (1.97)	
		95% CI	-4.6, 3.1	
		p-value	0.7119	
		Corrected Hedges' g (95% CI)	-0.05 (-0.32, 0.22)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	81 (44.0%)
		LS Mean (SE)	-2.1 (1.44)	-3.3 (1.50)
		95% CI	-4.9, 0.7	-6.2, -0.3
		Difference from placebo		
		LS Mean (SE)	1.2 (2.08)	
		95% CI	-2.9, 5.2	
		p-value	0.5777	
		Corrected Hedges' g (95% CI)	0.08 (-0.21, 0.38)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	90 (46.9%)	82 (44.6%)
		LS Mean (SE)	-3.2 (1.46)	-0.0 (1.52)
		95% CI	-6.0, -0.3	-3.0, 2.9
		Difference from placebo		
		LS Mean (SE)	-3.2 (2.10)	
		95% CI	-7.3, 1.0	
		p-value	0.1338	
		Corrected Hedges' g (95% CI)	-0.23 (-0.53, 0.07)	
Week 61	Change from Baseline	n (%)	79 (41.1%)	64 (34.8%)
		LS Mean (SE)	-2.6 (1.51)	-1.4 (1.63)
		95% CI	-5.6, 0.4	-4.6, 1.7
		Difference from placebo		
		LS Mean (SE)	-1.2 (2.22)	
		95% CI	-5.5, 3.2	
		p-value	0.6028	
		Corrected Hedges' g (95% CI)	-0.09 (-0.42, 0.24)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	71 (38.6%)
		LS Mean (SE)	-1.1 (1.52)	-0.7 (1.59)
		95% CI	-4.1, 1.9	-3.9, 2.4
		Difference from placebo		
		LS Mean (SE)	-0.4 (2.20)	
		95% CI	-4.7, 4.0	
		p-value	0.8680	
		Corrected Hedges' g (95% CI)	-0.03 (-0.35, 0.29)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	61 (33.2%)
		LS Mean (SE)	-0.7 (1.55)	-0.2 (1.67)
		95% CI	-3.8, 2.3	-3.4, 3.1
		Difference from placebo		
		LS Mean (SE)	-0.6 (2.28)	
		95% CI	-5.0, 3.9	
		p-value	0.8086	
		Corrected Hedges' g (95% CI)	-0.04 (-0.38, 0.30)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	65 (33.9%)	56 (30.4%)
		LS Mean (SE)	-2.0 (1.62)	-0.6 (1.73)
		95% CI	-5.2, 1.2	-4.0, 2.8
		Difference from placebo		
		LS Mean (SE)	-1.4 (2.38)	
		95% CI	-6.0, 3.3	
		p-value	0.5702	
		Corrected Hedges' g (95% CI)	-0.10 (-0.46, 0.25)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	-1.3 (1.62)	-1.7 (1.72)
		95% CI	-4.5, 1.8	-5.1, 1.6
		Difference from placebo		
		LS Mean (SE)	0.4 (2.36)	
		95% CI	-4.2, 5.0	
		p-value	0.8643	
		Corrected Hedges' g (95% CI)	0.03 (-0.32, 0.38)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	54 (28.1%)	48 (26.1%)
		LS Mean (SE)	-2.2 (1.73)	-0.3 (1.84)
		95% CI	-5.6, 1.2	-3.9, 3.3
		Difference from placebo		
		LS Mean (SE)	-1.9 (2.53)	
		95% CI	-6.8, 3.1	
		p-value	0.4637	
		Corrected Hedges' g (95% CI)	-0.14 (-0.53, 0.24)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	-2.7 (1.66)	-1.5 (1.80)
		95% CI	-5.9, 0.6	-5.1, 2.0
		Difference from placebo		
		LS Mean (SE)	-1.2 (2.45)	
		95% CI	-6.0, 3.7	
		p-value	0.6388	
		Corrected Hedges' g (95% CI)	-0.09 (-0.45, 0.28)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	42 (22.8%)
		LS Mean (SE)	-3.7 (1.74)	-1.1 (1.93)
		95% CI	-7.1, -0.3	-4.9, 2.7
		Difference from placebo		
		LS Mean (SE)	-2.6 (2.60)	
		95% CI	-7.7, 2.5	
		p-value	0.3144	
		Corrected Hedges' g (95% CI)	-0.20 (-0.61, 0.20)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	-0.9 (1.79)	3.8 (1.83)
		95% CI	-4.4, 2.6	0.2, 7.4
		Difference from placebo		
		LS Mean (SE)	-4.6 (2.56)	
		95% CI	-9.7, 0.4	
		p-value	0.0702	
		Corrected Hedges' g (95% CI)	-0.36 (-0.75, 0.03)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	41 (22.3%)
		LS Mean (SE)	-2.6 (1.81)	1.6 (1.96)
		95% CI	-6.1, 1.0	-2.2, 5.4
		Difference from placebo		
		LS Mean (SE)	-4.1 (2.67)	
		95% CI	-9.4, 1.1	
		p-value	0.1207	
		Corrected Hedges' g (95% CI)	-0.33 (-0.74, 0.09)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	50 (27.2%)
		LS Mean (SE)	-0.3 (1.82)	2.1 (1.85)
		95% CI	-3.9, 3.3	-1.5, 5.7
		Difference from placebo		
		LS Mean (SE)	-2.4 (2.60)	
		95% CI	-7.5, 2.7	
		p-value	0.3615	
		Corrected Hedges' g (95% CI)	-0.18 (-0.57, 0.21)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	41 (22.3%)
		LS Mean (SE)	-3.1 (1.89)	2.0 (1.96)
		95% CI	-6.8, 0.6	-1.8, 5.9
		Difference from placebo		
		LS Mean (SE)	-5.1 (2.73)	
		95% CI	-10.5, 0.2	
		p-value	0.0605	
		Corrected Hedges' g (95% CI)	-0.40 (-0.83, 0.03)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	42 (22.8%)
		LS Mean (SE)	-3.1 (1.88)	3.0 (1.97)
		95% CI	-6.8, 0.6	-0.9, 6.8
		Difference from placebo		
		LS Mean (SE)	-6.1 (2.73)	
		95% CI	-11.4, -0.7	
		p-value	0.0259	
		Corrected Hedges' g (95% CI)	-0.47 (-0.90, -0.05)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	-2.5 (1.90)	1.3 (2.08)
		95% CI	-6.2, 1.2	-2.8, 5.4
		Difference from placebo		
		LS Mean (SE)	-3.8 (2.82)	
		95% CI	-9.3, 1.7	
		p-value	0.1764	
		Corrected Hedges' g (95% CI)	-0.30 (-0.74, 0.14)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	30 (16.3%)
		LS Mean (SE)	-3.4 (2.04)	1.3 (2.28)
		95% CI	-7.4, 0.6	-3.2, 5.8
		Difference from placebo		
		LS Mean (SE)	-4.7 (3.08)	
		95% CI	-10.8, 1.3	
		p-value	0.1250	
		Corrected Hedges' g (95% CI)	-0.38 (-0.86, 0.11)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	25 (13.6%)
		LS Mean (SE)	-3.3 (2.11)	-2.5 (2.44)
		95% CI	-7.5, 0.8	-7.3, 2.3
		Difference from placebo		
		LS Mean (SE)	-0.8 (3.24)	
		95% CI	-7.2, 5.5	
		p-value	0.7985	
		Corrected Hedges' g (95% CI)	-0.07 (-0.58, 0.45)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	19 (10.3%)
		LS Mean (SE)	-3.6 (2.46)	-0.6 (2.80)
		95% CI	-8.4, 1.3	-6.1, 4.9
		Difference from placebo		
		LS Mean (SE)	-3.0 (3.62)	
		95% CI	-10.1, 4.1	
		p-value	0.4065	
		Corrected Hedges' g (95% CI)	-0.24 (-0.83, 0.36)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	0.4 (2.62)	-1.6 (3.03)
		95% CI	-4.8, 5.5	-7.6, 4.3
		Difference from placebo		
		LS Mean (SE)	2.0 (3.95)	
		95% CI	-5.8, 9.7	
		p-value	0.6157	
		Corrected Hedges' g (95% CI)	0.16 (-0.48, 0.80)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	10 (5.4%)
		LS Mean (SE)	4.6 (2.90)	-1.1 (3.85)
		95% CI	-1.1, 10.2	-8.6, 6.5
		Difference from placebo		
		LS Mean (SE)	5.6 (4.77)	
		95% CI	-3.7, 15.0	
		p-value	0.2369	
		Corrected Hedges' g (95% CI)	0.45 (-0.34, 1.24)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	9.3 (3.45)	-5.4 (3.68)
		95% CI	2.6, 16.1	-12.6, 1.8
		Difference from placebo		
		LS Mean (SE)	14.8 (5.09)	
		95% CI	4.8, 24.7	
		p-value	0.0038	
		Corrected Hedges' g (95% CI)	1.18 (0.29, 2.06)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	7 (3.8%)
		LS Mean (SE)	4.8 (4.01)	-7.1 (5.00)
		95% CI	-3.1, 12.6	-16.9, 2.7
		Difference from placebo		
		LS Mean (SE)	11.9 (6.61)	
		95% CI	-1.1, 24.8	
		p-value	0.0728	
		Corrected Hedges' g (95% CI)	0.89 (-0.14, 1.93)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	9.8 (5.26)	-6.7 (8.35)
		95% CI	-0.5, 20.1	-23.0, 9.7
		Difference from placebo		
		LS Mean (SE)	16.5 (9.72)	
		95% CI	-2.6, 35.5	
		p-value	0.0904	
		Corrected Hedges' g (95% CI)	1.18 (-0.57, 2.93)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	171 (92.9%)
		LS Mean (SE)	-0.5 (0.67)	-0.2 (0.75)
		95% CI	-1.8, 0.8	-1.7, 1.2
		Difference from placebo		
		LS Mean (SE)	-0.3 (1.03)	
		95% CI	-2.3, 1.8	
		p-value	0.7959	
		Corrected Hedges' g (95% CI)	-0.03 (-0.24, 0.18)	
Week 4	Change from Baseline	n (%)	177 (92.2%)	169 (91.8%)
		LS Mean (SE)	-0.3 (0.86)	-1.6 (0.88)
		95% CI	-2.0, 1.4	-3.3, 0.1
		Difference from placebo		
		LS Mean (SE)	1.3 (1.23)	
		95% CI	-1.1, 3.7	
		p-value	0.2877	
		Corrected Hedges' g (95% CI)	0.11 (-0.10, 0.33)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	169 (88.0%)	160 (87.0%)
		LS Mean (SE)	-1.2 (0.87)	-1.4 (0.89)
		95% CI	-3.0, 0.5	-3.1, 0.4
		Difference from placebo		
		LS Mean (SE)	0.1 (1.25)	
		95% CI	-2.3, 2.6	
		p-value	0.9155	
		Corrected Hedges' g (95% CI)	0.01 (-0.20, 0.23)	
Week 10	Change from Baseline	n (%)	165 (85.9%)	151 (82.1%)
		LS Mean (SE)	-1.0 (0.88)	-2.5 (0.91)
		95% CI	-2.8, 0.7	-4.3, -0.7
		Difference from placebo		
		LS Mean (SE)	1.5 (1.26)	
		95% CI	-1.0, 4.0	
		p-value	0.2443	
		Corrected Hedges' g (95% CI)	0.13 (-0.09, 0.35)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	143 (77.7%)
		LS Mean (SE)	-0.6 (0.89)	-1.5 (0.92)
		95% CI	-2.4, 1.1	-3.3, 0.3
		Difference from placebo		
		LS Mean (SE)	0.9 (1.28)	
		95% CI	-1.6, 3.4	
		p-value	0.4963	
		Corrected Hedges' g (95% CI)	0.08 (-0.15, 0.31)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	145 (78.8%)
		LS Mean (SE)	-0.9 (0.90)	-1.5 (0.92)
		95% CI	-2.7, 0.9	-3.3, 0.3
		Difference from placebo		
		LS Mean (SE)	0.6 (1.29)	
		95% CI	-1.9, 3.1	
		p-value	0.6455	
		Corrected Hedges' g (95% CI)	0.05 (-0.17, 0.28)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	145 (78.8%)
		LS Mean (SE)	-1.6 (0.90)	-2.8 (0.93)
		95% CI	-3.4, 0.1	-4.6, -1.0
		Difference from placebo		
		LS Mean (SE)	1.2 (1.29)	
		95% CI	-1.4, 3.7	
		p-value	0.3733	
		Corrected Hedges' g (95% CI)	0.10 (-0.12, 0.33)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	129 (70.1%)
		LS Mean (SE)	-3.2 (0.93)	-2.3 (0.96)
		95% CI	-5.0, -1.3	-4.2, -0.4
		Difference from placebo		
		LS Mean (SE)	-0.8 (1.34)	
		95% CI	-3.5, 1.8	
		p-value	0.5256	
		Corrected Hedges' g (95% CI)	-0.08 (-0.32, 0.16)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	127 (66.1%)	129 (70.1%)
		LS Mean (SE)	-2.4 (0.96)	-1.7 (0.97)
		95% CI	-4.3, -0.6	-3.6, 0.2
		Difference from placebo		
		LS Mean (SE)	-0.7 (1.36)	
		95% CI	-3.4, 2.0	
		p-value	0.6138	
		Corrected Hedges' g (95% CI)	-0.06 (-0.31, 0.18)	
Week 37	Change from Baseline	n (%)	113 (58.9%)	103 (56.0%)
		LS Mean (SE)	-2.4 (1.00)	-2.0 (1.04)
		95% CI	-4.4, -0.5	-4.0, 0.1
		Difference from placebo		
		LS Mean (SE)	-0.5 (1.44)	
		95% CI	-3.3, 2.4	
		p-value	0.7494	
		Corrected Hedges' g (95% CI)	-0.04 (-0.31, 0.22)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	106 (55.2%)	103 (56.0%)
		LS Mean (SE)	-1.7 (1.02)	-1.0 (1.05)
		95% CI	-3.7, 0.3	-3.0, 1.1
		Difference from placebo		
		LS Mean (SE)	-0.7 (1.46)	
		95% CI	-3.6, 2.1	
		p-value	0.6224	
		Corrected Hedges' g (95% CI)	-0.07 (-0.34, 0.20)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	79 (42.9%)
		LS Mean (SE)	-0.3 (1.07)	-1.1 (1.14)
		95% CI	-2.4, 1.8	-3.3, 1.1
		Difference from placebo		
		LS Mean (SE)	0.8 (1.56)	
		95% CI	-2.3, 3.9	
		p-value	0.6105	
		Corrected Hedges' g (95% CI)	0.08 (-0.22, 0.38)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	90 (46.9%)	80 (43.5%)
		LS Mean (SE)	-0.8 (1.09)	-1.5 (1.14)
		95% CI	-2.9, 1.4	-3.8, 0.7
		Difference from placebo		
		LS Mean (SE)	0.8 (1.58)	
		95% CI	-2.3, 3.9	
		p-value	0.6317	
		Corrected Hedges' g (95% CI)	0.07 (-0.23, 0.37)	
Week 61	Change from Baseline	n (%)	79 (41.1%)	62 (33.7%)
		LS Mean (SE)	-0.6 (1.13)	-1.4 (1.24)
		95% CI	-2.9, 1.6	-3.9, 1.0
		Difference from placebo		
		LS Mean (SE)	0.8 (1.68)	
		95% CI	-2.5, 4.1	
		p-value	0.6491	
		Corrected Hedges' g (95% CI)	0.08 (-0.26, 0.41)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	70 (38.0%)
		LS Mean (SE)	-1.1 (1.13)	-2.0 (1.20)
		95% CI	-3.3, 1.1	-4.4, 0.3
		Difference from placebo		
		LS Mean (SE)	0.9 (1.65)	
		95% CI	-2.3, 4.2	
		p-value	0.5767	
		Corrected Hedges' g (95% CI)	0.09 (-0.23, 0.41)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	60 (32.6%)
		LS Mean (SE)	-2.1 (1.16)	0.8 (1.27)
		95% CI	-4.3, 0.2	-1.7, 3.3
		Difference from placebo		
		LS Mean (SE)	-2.9 (1.72)	
		95% CI	-6.2, 0.5	
		p-value	0.0965	
		Corrected Hedges' g (95% CI)	-0.29 (-0.63, 0.06)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	64 (33.3%)	55 (29.9%)
		LS Mean (SE)	-0.7 (1.22)	-2.4 (1.33)
		95% CI	-3.1, 1.7	-5.0, 0.3
		Difference from placebo		
		LS Mean (SE)	1.7 (1.81)	
		95% CI	-1.9, 5.3	
		p-value	0.3479	
		Corrected Hedges' g (95% CI)	0.17 (-0.19, 0.53)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	56 (30.4%)
		LS Mean (SE)	-0.5 (1.21)	-2.8 (1.31)
		95% CI	-2.8, 1.9	-5.4, -0.2
		Difference from placebo		
		LS Mean (SE)	2.3 (1.78)	
		95% CI	-1.2, 5.8	
		p-value	0.1887	
		Corrected Hedges' g (95% CI)	0.24 (-0.12, 0.59)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	54 (28.1%)	47 (25.5%)
		LS Mean (SE)	0.4 (1.31)	-0.2 (1.40)
		95% CI	-2.1, 3.0	-3.0, 2.5
		Difference from placebo		
		LS Mean (SE)	0.7 (1.92)	
		95% CI	-3.1, 4.4	
		p-value	0.7337	
		Corrected Hedges' g (95% CI)	0.07 (-0.32, 0.46)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	51 (27.7%)
		LS Mean (SE)	1.8 (1.26)	-0.7 (1.37)
		95% CI	-0.7, 4.3	-3.4, 2.0
		Difference from placebo		
		LS Mean (SE)	2.5 (1.87)	
		95% CI	-1.2, 6.1	
		p-value	0.1869	
		Corrected Hedges' g (95% CI)	0.25 (-0.12, 0.62)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	41 (22.3%)
		LS Mean (SE)	-0.5 (1.31)	-0.2 (1.49)
		95% CI	-3.0, 2.1	-3.2, 2.7
		Difference from placebo		
		LS Mean (SE)	-0.2 (1.98)	
		95% CI	-4.1, 3.7	
		p-value	0.9174	
		Corrected Hedges' g (95% CI)	-0.02 (-0.43, 0.38)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	50 (27.2%)
		LS Mean (SE)	-1.4 (1.35)	0.6 (1.39)
		95% CI	-4.0, 1.3	-2.1, 3.4
		Difference from placebo		
		LS Mean (SE)	-2.0 (1.95)	
		95% CI	-5.8, 1.8	
		p-value	0.3019	
		Corrected Hedges' g (95% CI)	-0.20 (-0.60, 0.19)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	40 (21.7%)
		LS Mean (SE)	-1.5 (1.37)	-0.5 (1.49)
		95% CI	-4.2, 1.1	-3.5, 2.4
		Difference from placebo		
		LS Mean (SE)	-1.0 (2.03)	
		95% CI	-5.0, 3.0	
		p-value	0.6229	
		Corrected Hedges' g (95% CI)	-0.10 (-0.52, 0.31)	
Week 121	Change from Baseline	n (%)	49 (25.5%)	49 (26.6%)
		LS Mean (SE)	1.9 (1.38)	-1.1 (1.39)
		95% CI	-0.9, 4.6	-3.9, 1.6
		Difference from placebo		
		LS Mean (SE)	3.0 (1.96)	
		95% CI	-0.9, 6.8	
		p-value	0.1272	
		Corrected Hedges' g (95% CI)	0.31 (-0.09, 0.70)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	40 (21.7%)
		LS Mean (SE)	-1.1 (1.43)	1.1 (1.51)
		95% CI	-3.9, 1.7	-1.9, 4.0
		Difference from placebo		
		LS Mean (SE)	-2.2 (2.08)	
		95% CI	-6.2, 1.9	
		p-value	0.3007	
		Corrected Hedges' g (95% CI)	-0.22 (-0.65, 0.21)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	41 (22.3%)
		LS Mean (SE)	0.1 (1.41)	-0.5 (1.49)
		95% CI	-2.7, 2.8	-3.4, 2.4
		Difference from placebo		
		LS Mean (SE)	0.6 (2.06)	
		95% CI	-3.5, 4.6	
		p-value	0.7883	
		Corrected Hedges' g (95% CI)	0.06 (-0.36, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	35 (19.0%)
		LS Mean (SE)	0.1 (1.43)	1.9 (1.62)
		95% CI	-2.7, 2.9	-1.3, 5.0
		Difference from placebo		
		LS Mean (SE)	-1.8 (2.16)	
		95% CI	-6.0, 2.5	
		p-value	0.4153	
		Corrected Hedges' g (95% CI)	-0.18 (-0.62, 0.26)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	29 (15.8%)
		LS Mean (SE)	-0.0 (1.54)	0.3 (1.73)
		95% CI	-3.0, 3.0	-3.1, 3.7
		Difference from placebo		
		LS Mean (SE)	-0.3 (2.32)	
		95% CI	-4.8, 4.3	
		p-value	0.9041	
		Corrected Hedges' g (95% CI)	-0.03 (-0.52, 0.46)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	-1.9 (1.61)	1.4 (1.91)
		95% CI	-5.0, 1.3	-2.3, 5.2
		Difference from placebo		
		LS Mean (SE)	-3.3 (2.52)	
		95% CI	-8.2, 1.6	
		p-value	0.1906	
		Corrected Hedges' g (95% CI)	-0.35 (-0.87, 0.18)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	18 (9.8%)
		LS Mean (SE)	-2.2 (1.81)	3.1 (2.17)
		95% CI	-5.7, 1.4	-1.1, 7.4
		Difference from placebo		
		LS Mean (SE)	-5.3 (2.80)	
		95% CI	-10.8, 0.2	
		p-value	0.0587	
		Corrected Hedges' g (95% CI)	-0.56 (-1.18, 0.05)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	16 (8.7%)
		LS Mean (SE)	-1.4 (1.99)	0.5 (2.29)
		95% CI	-5.3, 2.5	-4.0, 5.0
		Difference from placebo		
		LS Mean (SE)	-1.9 (3.03)	
		95% CI	-7.8, 4.0	
		p-value	0.5310	
		Corrected Hedges' g (95% CI)	-0.20 (-0.86, 0.45)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	10 (5.4%)
		LS Mean (SE)	2.6 (2.21)	3.6 (2.80)
		95% CI	-1.8, 6.9	-1.9, 9.1
		Difference from placebo		
		LS Mean (SE)	-1.0 (3.57)	
		95% CI	-8.0, 6.0	
		p-value	0.7789	
		Corrected Hedges' g (95% CI)	-0.11 (-0.89, 0.67)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	0.3 (2.63)	1.9 (2.84)
		95% CI	-4.8, 5.5	-3.7, 7.4
		Difference from placebo		
		LS Mean (SE)	-1.5 (3.83)	
		95% CI	-9.1, 6.0	
		p-value	0.6859	
		Corrected Hedges' g (95% CI)	-0.16 (-0.98, 0.66)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	7 (3.8%)
		LS Mean (SE)	4.0 (3.04)	-4.5 (3.91)
		95% CI	-2.0, 9.9	-12.2, 3.1
		Difference from placebo		
		LS Mean (SE)	8.5 (4.90)	
		95% CI	-1.1, 18.1	
		p-value	0.0831	
		Corrected Hedges' g (95% CI)	0.83 (-0.20, 1.86)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	2.7 (5.54)	13.8 (10.36)
		95% CI	-8.2, 13.6	-6.6, 34.1
		Difference from placebo		
		LS Mean (SE)	-11.0 (14.21)	
		95% CI	-38.9, 16.8	
		p-value	0.4372	
		Corrected Hedges' g (95% CI)	-0.72 (-2.40, 0.96)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	178 (92.7%)	173 (94.0%)
		LS Mean (SE)	7.1 (1.59)	4.8 (1.67)
		95% CI	4.0, 10.2	1.5, 8.1
		Difference from placebo		
		LS Mean (SE)	2.3 (2.31)	
		95% CI	-2.2, 6.8	
		p-value	0.3177	
		Corrected Hedges' g (95% CI)	0.11 (-0.10, 0.32)	
Week 4	Change from Baseline	n (%)	173 (90.1%)	170 (92.4%)
		LS Mean (SE)	17.3 (1.89)	11.8 (1.91)
		95% CI	13.6, 21.0	8.0, 15.5
		Difference from placebo		
		LS Mean (SE)	5.5 (2.69)	
		95% CI	0.2, 10.8	
		p-value	0.0401	
		Corrected Hedges' g (95% CI)	0.22 (0.01, 0.43)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	167 (87.0%)	162 (88.0%)
		LS Mean (SE)	17.3 (1.90)	12.9 (1.93)
		95% CI	13.6, 21.0	9.1, 16.7
		Difference from placebo		
		LS Mean (SE)	4.4 (2.71)	
		95% CI	-0.9, 9.7	
		p-value	0.1032	
		Corrected Hedges' g (95% CI)	0.18 (-0.04, 0.40)	
Week 10	Change from Baseline	n (%)	162 (84.4%)	152 (82.6%)
		LS Mean (SE)	15.0 (1.91)	12.7 (1.96)
		95% CI	11.3, 18.8	8.8, 16.5
		Difference from placebo		
		LS Mean (SE)	2.3 (2.74)	
		95% CI	-3.0, 7.7	
		p-value	0.3945	
		Corrected Hedges' g (95% CI)	0.10 (-0.13, 0.32)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	153 (79.7%)	144 (78.3%)
		LS Mean (SE)	18.3 (1.94)	12.2 (1.98)
		95% CI	14.5, 22.1	8.3, 16.1
		Difference from placebo		
		LS Mean (SE)	6.1 (2.77)	
		95% CI	0.7, 11.5	
		p-value	0.0281	
		Corrected Hedges' g (95% CI)	0.25 (0.03, 0.48)	
Week 16	Change from Baseline	n (%)	148 (77.1%)	147 (79.9%)
		LS Mean (SE)	18.4 (1.95)	11.9 (1.98)
		95% CI	14.5, 22.2	8.0, 15.7
		Difference from placebo		
		LS Mean (SE)	6.5 (2.78)	
		95% CI	1.1, 12.0	
		p-value	0.0194	
		Corrected Hedges' g (95% CI)	0.27 (0.04, 0.50)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	149 (77.6%)	145 (78.8%)
		LS Mean (SE)	18.7 (1.96)	14.0 (1.99)
		95% CI	14.9, 22.6	10.1, 17.9
		Difference from placebo		
		LS Mean (SE)	4.7 (2.79)	
		95% CI	-0.8, 10.2	
		p-value	0.0918	
		Corrected Hedges' g (95% CI)	0.20 (-0.03, 0.43)	
Week 25	Change from Baseline	n (%)	135 (70.3%)	128 (69.6%)
		LS Mean (SE)	14.6 (2.00)	10.1 (2.04)
		95% CI	10.7, 18.6	6.0, 14.1
		Difference from placebo		
		LS Mean (SE)	4.6 (2.86)	
		95% CI	-1.1, 10.2	
		p-value	0.1112	
		Corrected Hedges' g (95% CI)	0.20 (-0.05, 0.44)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	125 (65.1%)	129 (70.1%)
		LS Mean (SE)	12.8 (2.05)	8.4 (2.06)
		95% CI	8.8, 16.8	4.4, 12.5
		Difference from placebo		
		LS Mean (SE)	4.3 (2.90)	
		95% CI	-1.3, 10.0	
		p-value	0.1344	
		Corrected Hedges' g (95% CI)	0.19 (-0.06, 0.43)	
Week 37	Change from Baseline	n (%)	111 (57.8%)	106 (57.6%)
		LS Mean (SE)	10.3 (2.11)	6.9 (2.15)
		95% CI	6.2, 14.5	2.7, 11.2
		Difference from placebo		
		LS Mean (SE)	3.4 (3.01)	
		95% CI	-2.5, 9.3	
		p-value	0.2587	
		Corrected Hedges' g (95% CI)	0.15 (-0.11, 0.42)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	104 (54.2%)	102 (55.4%)
		LS Mean (SE)	10.1 (2.15)	4.5 (2.19)
		95% CI	5.9, 14.3	0.2, 8.8
		Difference from placebo		
		LS Mean (SE)	5.6 (3.07)	
		95% CI	-0.5, 11.6	
		p-value	0.0699	
		Corrected Hedges' g (95% CI)	0.25 (-0.02, 0.53)	
Week 49	Change from Baseline	n (%)	91 (47.4%)	80 (43.5%)
		LS Mean (SE)	7.1 (2.23)	3.1 (2.33)
		95% CI	2.7, 11.5	-1.5, 7.7
		Difference from placebo		
		LS Mean (SE)	4.0 (3.22)	
		95% CI	-2.3, 10.3	
		p-value	0.2158	
		Corrected Hedges' g (95% CI)	0.19 (-0.11, 0.49)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	87 (45.3%)	79 (42.9%)
		LS Mean (SE)	7.2 (2.27)	4.5 (2.35)
		95% CI	2.8, 11.7	-0.1, 9.1
		Difference from placebo		
		LS Mean (SE)	2.7 (3.27)	
		95% CI	-3.7, 9.1	
		p-value	0.4047	
		Corrected Hedges' g (95% CI)	0.13 (-0.18, 0.43)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	64 (34.8%)
		LS Mean (SE)	4.6 (2.34)	1.8 (2.48)
		95% CI	0.0, 9.2	-3.1, 6.7
		Difference from placebo		
		LS Mean (SE)	2.8 (3.41)	
		95% CI	-3.9, 9.5	
		p-value	0.4152	
		Corrected Hedges' g (95% CI)	0.14 (-0.19, 0.47)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	72 (39.1%)
		LS Mean (SE)	6.5 (2.33)	3.3 (2.43)
		95% CI	1.9, 11.0	-1.5, 8.0
		Difference from placebo		
		LS Mean (SE)	3.2 (3.36)	
		95% CI	-3.4, 9.8	
		p-value	0.3399	
		Corrected Hedges' g (95% CI)	0.15 (-0.16, 0.47)	
Week 73	Change from Baseline	n (%)	73 (38.0%)	61 (33.2%)
		LS Mean (SE)	8.9 (2.39)	8.2 (2.54)
		95% CI	4.2, 13.6	3.2, 13.2
		Difference from placebo		
		LS Mean (SE)	0.7 (3.50)	
		95% CI	-6.2, 7.6	
		p-value	0.8399	
		Corrected Hedges' g (95% CI)	0.03 (-0.31, 0.37)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	64 (33.3%)	55 (29.9%)
		LS Mean (SE)	5.2 (2.48)	7.6 (2.63)
		95% CI	0.3, 10.0	2.5, 12.8
		Difference from placebo		
		LS Mean (SE)	-2.5 (3.62)	
		95% CI	-9.6, 4.6	
		p-value	0.4955	
		Corrected Hedges' g (95% CI)	-0.12 (-0.49, 0.24)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	3.3 (2.46)	3.0 (2.61)
		95% CI	-1.5, 8.2	-2.1, 8.1
		Difference from placebo		
		LS Mean (SE)	0.3 (3.59)	
		95% CI	-6.7, 7.4	
		p-value	0.9274	
		Corrected Hedges' g (95% CI)	0.02 (-0.33, 0.37)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	54 (28.1%)	47 (25.5%)
		LS Mean (SE)	4.7 (2.62)	5.2 (2.78)
		95% CI	-0.4, 9.9	-0.2, 10.7
		Difference from placebo		
		LS Mean (SE)	-0.5 (3.82)	
		95% CI	-8.0, 7.0	
		p-value	0.8937	
		Corrected Hedges' g (95% CI)	-0.03 (-0.42, 0.36)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	4.0 (2.53)	2.2 (2.73)
		95% CI	-1.0, 8.9	-3.1, 7.6
		Difference from placebo		
		LS Mean (SE)	1.7 (3.72)	
		95% CI	-5.6, 9.0	
		p-value	0.6417	
		Corrected Hedges' g (95% CI)	0.09 (-0.28, 0.45)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	42 (22.8%)
		LS Mean (SE)	8.7 (2.64)	0.4 (2.89)
		95% CI	3.5, 13.9	-5.3, 6.0
		Difference from placebo		
		LS Mean (SE)	8.3 (3.92)	
		95% CI	0.7, 16.0	
		p-value	0.0335	
		Corrected Hedges' g (95% CI)	0.43 (0.02, 0.84)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	50 (27.2%)
		LS Mean (SE)	4.8 (2.70)	5.3 (2.77)
		95% CI	-0.5, 10.2	-0.1, 10.8
		Difference from placebo		
		LS Mean (SE)	-0.5 (3.87)	
		95% CI	-8.1, 7.1	
		p-value	0.9029	
		Corrected Hedges' g (95% CI)	-0.02 (-0.41, 0.37)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	40 (21.7%)
		LS Mean (SE)	4.1 (2.74)	2.0 (2.95)
		95% CI	-1.3, 9.5	-3.8, 7.8
		Difference from placebo		
		LS Mean (SE)	2.1 (4.03)	
		95% CI	-5.8, 10.1	
		p-value	0.5953	
		Corrected Hedges' g (95% CI)	0.11 (-0.31, 0.53)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	49 (26.6%)
		LS Mean (SE)	4.8 (2.73)	3.1 (2.80)
		95% CI	-0.6, 10.2	-2.4, 8.6
		Difference from placebo		
		LS Mean (SE)	1.7 (3.92)	
		95% CI	-6.0, 9.4	
		p-value	0.6633	
		Corrected Hedges' g (95% CI)	0.09 (-0.31, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	39 (21.2%)
		LS Mean (SE)	5.5 (2.84)	4.4 (2.99)
		95% CI	-0.0, 11.1	-1.4, 10.3
		Difference from placebo		
		LS Mean (SE)	1.1 (4.13)	
		95% CI	-7.0, 9.2	
		p-value	0.7854	
		Corrected Hedges' g (95% CI)	0.06 (-0.37, 0.49)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	43 (23.4%)
		LS Mean (SE)	4.1 (2.82)	3.1 (2.93)
		95% CI	-1.5, 9.6	-2.7, 8.8
		Difference from placebo		
		LS Mean (SE)	1.0 (4.07)	
		95% CI	-7.0, 9.0	
		p-value	0.8100	
		Corrected Hedges' g (95% CI)	0.05 (-0.37, 0.47)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	35 (19.0%)
		LS Mean (SE)	1.8 (2.85)	4.1 (3.14)
		95% CI	-3.8, 7.4	-2.1, 10.2
		Difference from placebo		
		LS Mean (SE)	-2.3 (4.24)	
		95% CI	-10.6, 6.0	
		p-value	0.5926	
		Corrected Hedges' g (95% CI)	-0.12 (-0.56, 0.32)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	30 (16.3%)
		LS Mean (SE)	2.0 (3.04)	0.4 (3.33)
		95% CI	-4.0, 8.0	-6.1, 7.0
		Difference from placebo		
		LS Mean (SE)	1.6 (4.51)	
		95% CI	-7.3, 10.4	
		p-value	0.7281	
		Corrected Hedges' g (95% CI)	0.08 (-0.40, 0.57)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	24 (13.0%)
		LS Mean (SE)	3.3 (3.15)	3.9 (3.65)
		95% CI	-2.9, 9.4	-3.3, 11.0
		Difference from placebo		
		LS Mean (SE)	-0.6 (4.82)	
		95% CI	-10.0, 8.9	
		p-value	0.9024	
		Corrected Hedges' g (95% CI)	-0.03 (-0.55, 0.49)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	20 (10.9%)
		LS Mean (SE)	-2.0 (3.56)	3.5 (3.96)
		95% CI	-9.0, 5.0	-4.3, 11.2
		Difference from placebo		
		LS Mean (SE)	-5.4 (5.29)	
		95% CI	-15.8, 4.9	
		p-value	0.3044	
		Corrected Hedges' g (95% CI)	-0.30 (-0.88, 0.29)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	5.5 (3.83)	1.6 (4.27)
		95% CI	-2.0, 13.0	-6.8, 10.0
		Difference from placebo		
		LS Mean (SE)	3.9 (5.73)	
		95% CI	-7.3, 15.1	
		p-value	0.4961	
		Corrected Hedges' g (95% CI)	0.22 (-0.42, 0.86)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	11 (6.0%)
		LS Mean (SE)	2.6 (4.24)	2.3 (5.08)
		95% CI	-5.7, 10.9	-7.6, 12.3
		Difference from placebo		
		LS Mean (SE)	0.3 (6.63)	
		95% CI	-12.7, 13.2	
		p-value	0.9696	
		Corrected Hedges' g (95% CI)	0.01 (-0.74, 0.77)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	-0.1 (5.06)	-1.0 (6.13)
		95% CI	-10.0, 9.8	-13.0, 11.0
		Difference from placebo		
		LS Mean (SE)	0.9 (7.61)	
		95% CI	-14.0, 15.8	
		p-value	0.9068	
		Corrected Hedges' g (95% CI)	0.05 (-0.77, 0.86)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	-0.9 (5.87)	-4.4 (6.77)
		95% CI	-12.4, 10.6	-17.7, 8.8
		Difference from placebo		
		LS Mean (SE)	3.6 (8.59)	
		95% CI	-13.3, 20.4	
		p-value	0.6792	
		Corrected Hedges' g (95% CI)	0.18 (-0.77, 1.14)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	-6.5 (7.97)	-9.4 (12.42)
		95% CI	-22.2, 9.1	-33.7, 15.0
		Difference from placebo		
		LS Mean (SE)	2.9 (15.56)	
		95% CI	-27.7, 33.4	
		p-value	0.8542	
		Corrected Hedges' g (95% CI)	0.14 (-1.51, 1.78)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	32 (16.7%)	36 (19.6%)
		LS Mean (SE)	4.8 (3.04)	3.5 (3.27)
		95% CI	-1.3, 10.8	-3.0, 10.0
		Difference from placebo		
		LS Mean (SE)	1.3 (4.39)	
		95% CI	-7.4, 10.0	
		p-value	0.7716	
		Corrected Hedges' g (95% CI)	0.07 (-0.41, 0.54)	
Week 4	Change from Baseline	n (%)	20 (10.4%)	24 (13.0%)
		LS Mean (SE)	0.1 (4.09)	3.8 (3.78)
		95% CI	-8.0, 8.2	-3.7, 11.2
		Difference from placebo		
		LS Mean (SE)	-3.7 (5.52)	
		95% CI	-14.6, 7.2	
		p-value	0.5082	
		Corrected Hedges' g (95% CI)	-0.20 (-0.79, 0.40)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	20 (10.4%)	23 (12.5%)
		LS Mean (SE)	16.5 (4.08)	3.5 (3.78)
		95% CI	8.5, 24.6	-4.0, 10.9
		Difference from placebo		
		LS Mean (SE)	13.0 (5.53)	
		95% CI	2.1, 23.9	
		p-value	0.0195	
		Corrected Hedges' g (95% CI)	0.70 (0.09, 1.32)	
Week 10	Change from Baseline	n (%)	17 (8.9%)	20 (10.9%)
		LS Mean (SE)	16.1 (4.28)	0.8 (3.94)
		95% CI	7.7, 24.5	-6.9, 8.6
		Difference from placebo		
		LS Mean (SE)	15.3 (5.81)	
		95% CI	3.8, 26.7	
		p-value	0.0091	
		Corrected Hedges' g (95% CI)	0.85 (0.17, 1.52)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	15 (7.8%)	23 (12.5%)
		LS Mean (SE)	-0.8 (4.47)	3.8 (3.84)
		95% CI	-9.6, 8.0	-3.8, 11.3
		Difference from placebo		
		LS Mean (SE)	-4.6 (5.89)	
		95% CI	-16.2, 7.0	
		p-value	0.4385	
		Corrected Hedges' g (95% CI)	-0.25 (-0.90, 0.40)	
Week 16	Change from Baseline	n (%)	13 (6.8%)	22 (12.0%)
		LS Mean (SE)	3.5 (4.82)	4.8 (3.91)
		95% CI	-6.0, 12.9	-2.9, 12.5
		Difference from placebo		
		LS Mean (SE)	-1.3 (6.14)	
		95% CI	-13.4, 10.7	
		p-value	0.8273	
		Corrected Hedges' g (95% CI)	-0.07 (-0.76, 0.61)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	16 (8.3%)	16 (8.7%)
		LS Mean (SE)	-2.0 (4.66)	-3.5 (4.37)
		95% CI	-11.2, 7.2	-12.2, 5.1
		Difference from placebo		
		LS Mean (SE)	1.5 (6.18)	
		95% CI	-10.6, 13.7	
		p-value	0.8037	
		Corrected Hedges' g (95% CI)	0.08 (-0.61, 0.78)	
Week 25	Change from Baseline	n (%)	17 (8.9%)	15 (8.2%)
		LS Mean (SE)	3.2 (4.24)	10.8 (4.47)
		95% CI	-5.1, 11.6	2.0, 19.6
		Difference from placebo		
		LS Mean (SE)	-7.6 (6.14)	
		95% CI	-19.7, 4.5	
		p-value	0.2179	
		Corrected Hedges' g (95% CI)	-0.43 (-1.13, 0.28)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	20 (10.4%)	15 (8.2%)
		LS Mean (SE)	10.3 (4.11)	5.5 (4.46)
		95% CI	2.2, 18.4	-3.3, 14.3
		Difference from placebo		
		LS Mean (SE)	4.8 (6.06)	
		95% CI	-7.2, 16.7	
		p-value	0.4322	
		Corrected Hedges' g (95% CI)	0.26 (-0.41, 0.93)	
Week 37	Change from Baseline	n (%)	14 (7.3%)	11 (6.0%)
		LS Mean (SE)	3.0 (4.58)	11.5 (4.96)
		95% CI	-6.1, 12.0	1.7, 21.2
		Difference from placebo		
		LS Mean (SE)	-8.5 (6.73)	
		95% CI	-21.8, 4.7	
		p-value	0.2063	
		Corrected Hedges' g (95% CI)	-0.49 (-1.29, 0.31)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	18 (9.4%)	9 (4.9%)
		LS Mean (SE)	3.8 (4.29)	10.1 (5.45)
		95% CI	-4.7, 12.2	-0.7, 20.8
		Difference from placebo		
		LS Mean (SE)	-6.3 (6.99)	
		95% CI	-20.1, 7.4	
		p-value	0.3665	
		Corrected Hedges' g (95% CI)	-0.35 (-1.15, 0.46)	
Week 49	Change from Baseline	n (%)	11 (5.7%)	8 (4.3%)
		LS Mean (SE)	2.7 (4.96)	6.5 (5.83)
		95% CI	-7.0, 12.5	-5.0, 17.9
		Difference from placebo		
		LS Mean (SE)	-3.7 (7.70)	
		95% CI	-18.9, 11.4	
		p-value	0.6304	
		Corrected Hedges' g (95% CI)	-0.22 (-1.13, 0.70)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	11 (5.7%)	6 (3.3%)
		LS Mean (SE)	4.5 (5.10)	9.6 (6.38)
		95% CI	-5.5, 14.5	-2.9, 22.2
		Difference from placebo		
		LS Mean (SE)	-5.2 (8.25)	
		95% CI	-21.4, 11.1	
		p-value	0.5315	
		Corrected Hedges' g (95% CI)	-0.30 (-1.30, 0.70)	
Week 61	Change from Baseline	n (%)	8 (4.2%)	6 (3.3%)
		LS Mean (SE)	4.7 (5.89)	4.0 (6.43)
		95% CI	-6.9, 16.2	-8.7, 16.6
		Difference from placebo		
		LS Mean (SE)	0.7 (8.88)	
		95% CI	-16.8, 18.2	
		p-value	0.9379	
		Corrected Hedges' g (95% CI)	0.04 (-1.02, 1.10)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	6 (3.1%)	5 (2.7%)
		LS Mean (SE)	6.4 (6.52)	6.1 (6.98)
		95% CI	-6.4, 19.3	-7.6, 19.8
		Difference from placebo		
		LS Mean (SE)	0.3 (9.70)	
		95% CI	-18.7, 19.4	
		p-value	0.9718	
		Corrected Hedges' g (95% CI)	0.02 (-1.17, 1.21)	
Week 73	Change from Baseline	n (%)	7 (3.6%)	3 (1.6%)
		LS Mean (SE)	7.8 (6.07)	13.4 (8.93)
		95% CI	-4.2, 19.7	-4.1, 31.0
		Difference from placebo		
		LS Mean (SE)	-5.6 (10.57)	
		95% CI	-26.4, 15.2	
		p-value	0.5958	
		Corrected Hedges' g (95% CI)	-0.32 (-1.68, 1.04)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	6 (3.1%)	3 (1.6%)
		LS Mean (SE)	5.8 (6.53)	-2.2 (10.63)
		95% CI	-7.1, 18.6	-23.1, 18.7
		Difference from placebo		
		LS Mean (SE)	8.0 (11.67)	
		95% CI	-15.0, 30.9	
		p-value	0.4950	
		Corrected Hedges' g (95% CI)	0.42 (-0.98, 1.82)	
Week 85	Change from Baseline	n (%)	4 (2.1%)	5 (2.7%)
		LS Mean (SE)	3.6 (7.60)	2.5 (7.05)
		95% CI	-11.3, 18.6	-11.4, 16.3
		Difference from placebo		
		LS Mean (SE)	1.2 (10.29)	
		95% CI	-19.1, 21.4	
		p-value	0.9102	
		Corrected Hedges' g (95% CI)	0.07 (-1.25, 1.38)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	4 (2.1%)	2 (1.1%)
		LS Mean (SE)	9.2 (12.62)	-6.5 (17.60)
		95% CI	-15.6, 34.1	-41.1, 28.1
		Difference from placebo		
		LS Mean (SE)	15.8 (13.54)	
		95% CI	-10.8, 42.4	
		p-value	0.2445	
		Corrected Hedges' g (95% CI)	0.50 (-1.22, 2.22)	
Week 97	Change from Baseline	n (%)	6 (3.1%)	3 (1.6%)
		LS Mean (SE)	-0.6 (7.20)	1.6 (8.65)
		95% CI	-14.7, 13.6	-15.5, 18.6
		Difference from placebo		
		LS Mean (SE)	-2.1 (11.19)	
		95% CI	-24.1, 19.9	
		p-value	0.8500	
		Corrected Hedges' g (95% CI)	-0.11 (-1.50, 1.28)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	6 (3.1%)	2 (1.1%)
		LS Mean (SE)	9.3 (7.72)	-2.7 (14.43)
		95% CI	-5.9, 24.4	-31.1, 25.7
		Difference from placebo		
		LS Mean (SE)	12.0 (13.57)	
		95% CI	-14.7, 38.6	
		p-value	0.3783	
		Corrected Hedges' g (95% CI)	0.54 (-1.08, 2.17)	
Week 115	Change from Baseline	n (%)	4 (2.1%)	2 (1.1%)
		LS Mean (SE)	-1.2 (7.54)	-0.6 (10.20)
		95% CI	-16.1, 13.6	-20.6, 19.5
		Difference from placebo		
		LS Mean (SE)	-0.7 (12.70)	
		95% CI	-25.6, 24.3	
		p-value	0.9569	
		Corrected Hedges' g (95% CI)	-0.04 (-1.73, 1.66)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 121	Change from Baseline	n (%)	3 (1.6%)	4 (2.2%)
		LS Mean (SE)	5.5 (8.63)	-0.5 (7.98)
		95% CI	-11.5, 22.4	-16.2, 15.2
		Difference from placebo		
		LS Mean (SE)	6.0 (11.69)	
		95% CI	-17.0, 29.0	
		p-value	0.6101	
		Corrected Hedges' g (95% CI)	0.32 (-1.18, 1.83)	
Week 127	Change from Baseline	n (%)	4 (2.1%)	3 (1.6%)
		LS Mean (SE)	-1.7 (8.06)	7.7 (11.33)
		95% CI	-17.6, 14.1	-14.5, 30.0
		Difference from placebo		
		LS Mean (SE)	-9.5 (12.50)	
		95% CI	-34.0, 15.1	
		p-value	0.4499	
		Corrected Hedges' g (95% CI)	-0.45 (-1.97, 1.06)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 133	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	3.0 (7.10)	-0.7 (10.52)
		95% CI	-10.9, 17.0	-21.4, 20.0
		Difference from placebo		
		LS Mean (SE)	3.7 (12.77)	
		95% CI	-21.4, 28.8	
		p-value	0.7711	
		Corrected Hedges' g (95% CI)	0.20 (-1.44, 1.84)	
Week 145	Change from Baseline	n (%)	4 (2.1%)	2 (1.1%)
		LS Mean (SE)	6.4 (8.13)	-2.1 (10.94)
		95% CI	-9.6, 22.4	-23.6, 19.4
		Difference from placebo		
		LS Mean (SE)	8.5 (13.16)	
		95% CI	-17.4, 34.4	
		p-value	0.5197	
		Corrected Hedges' g (95% CI)	0.42 (-1.29, 2.14)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	180 (93.8%)	171 (92.9%)
		LS Mean (SE)	-0.6 (1.41)	-2.5 (1.53)
		95% CI	-3.3, 2.2	-5.5, 0.5
		Difference from placebo		
		LS Mean (SE)	1.9 (2.10)	
		95% CI	-2.2, 6.1	
		p-value	0.3579	
		Corrected Hedges' g (95% CI)	0.10 (-0.11, 0.31)	
Week 4	Change from Baseline	n (%)	174 (90.6%)	169 (91.8%)
		LS Mean (SE)	-2.9 (1.85)	-6.1 (1.89)
		95% CI	-6.5, 0.8	-9.8, -2.4
		Difference from placebo		
		LS Mean (SE)	3.3 (2.64)	
		95% CI	-1.9, 8.4	
		p-value	0.2180	
		Corrected Hedges' g (95% CI)	0.13 (-0.08, 0.34)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	168 (87.5%)	160 (87.0%)
		LS Mean (SE)	-5.9 (1.87)	-8.8 (1.92)
		95% CI	-9.5, -2.2	-12.6, -5.0
		Difference from placebo		
		LS Mean (SE)	2.9 (2.68)	
		95% CI	-2.3, 8.2	
		p-value	0.2768	
		Corrected Hedges' g (95% CI)	0.12 (-0.10, 0.34)	
Week 10	Change from Baseline	n (%)	164 (85.4%)	150 (81.5%)
		LS Mean (SE)	-8.6 (1.88)	-9.2 (1.96)
		95% CI	-12.3, -4.9	-13.1, -5.4
		Difference from placebo		
		LS Mean (SE)	0.6 (2.72)	
		95% CI	-4.7, 5.9	
		p-value	0.8278	
		Corrected Hedges' g (95% CI)	0.02 (-0.20, 0.25)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	156 (81.3%)	142 (77.2%)
		LS Mean (SE)	-5.3 (1.91)	-7.3 (1.99)
		95% CI	-9.1, -1.6	-11.2, -3.4
		Difference from placebo		
		LS Mean (SE)	1.9 (2.76)	
		95% CI	-3.5, 7.3	
		p-value	0.4879	
		Corrected Hedges' g (95% CI)	0.08 (-0.15, 0.31)	
Week 16	Change from Baseline	n (%)	151 (78.6%)	144 (78.3%)
		LS Mean (SE)	-7.1 (1.93)	-4.6 (1.98)
		95% CI	-10.9, -3.3	-8.5, -0.7
		Difference from placebo		
		LS Mean (SE)	-2.5 (2.77)	
		95% CI	-8.0, 2.9	
		p-value	0.3593	
		Corrected Hedges' g (95% CI)	-0.11 (-0.33, 0.12)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	152 (79.2%)	145 (78.8%)
		LS Mean (SE)	-6.6 (1.93)	-6.6 (1.99)
		95% CI	-10.4, -2.8	-10.5, -2.7
		Difference from placebo		
		LS Mean (SE)	0.0 (2.77)	
		95% CI	-5.4, 5.5	
		p-value	0.9908	
		Corrected Hedges' g (95% CI)	0.00 (-0.23, 0.23)	
Week 25	Change from Baseline	n (%)	137 (71.4%)	129 (70.1%)
		LS Mean (SE)	-2.3 (2.00)	-4.1 (2.06)
		95% CI	-6.2, 1.7	-8.2, -0.1
		Difference from placebo		
		LS Mean (SE)	1.9 (2.87)	
		95% CI	-3.7, 7.5	
		p-value	0.5116	
		Corrected Hedges' g (95% CI)	0.08 (-0.16, 0.32)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	126 (65.6%)	129 (70.1%)
		LS Mean (SE)	-1.8 (2.06)	-2.7 (2.07)
		95% CI	-5.8, 2.3	-6.8, 1.4
		Difference from placebo		
		LS Mean (SE)	0.9 (2.92)	
		95% CI	-4.8, 6.7	
		p-value	0.7474	
		Corrected Hedges' g (95% CI)	0.04 (-0.21, 0.29)	
Week 37	Change from Baseline	n (%)	112 (58.3%)	103 (56.0%)
		LS Mean (SE)	-3.1 (2.14)	-2.2 (2.23)
		95% CI	-7.3, 1.1	-6.6, 2.2
		Difference from placebo		
		LS Mean (SE)	-0.8 (3.09)	
		95% CI	-6.9, 5.2	
		p-value	0.7849	
		Corrected Hedges' g (95% CI)	-0.04 (-0.30, 0.23)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	105 (54.7%)	103 (56.0%)
		LS Mean (SE)	-2.4 (2.20)	-4.6 (2.25)
		95% CI	-6.7, 2.0	-9.0, -0.2
		Difference from placebo		
		LS Mean (SE)	2.2 (3.14)	
		95% CI	-3.9, 8.4	
		p-value	0.4765	
		Corrected Hedges' g (95% CI)	0.10 (-0.17, 0.37)	
Week 49	Change from Baseline	n (%)	91 (47.4%)	80 (43.5%)
		LS Mean (SE)	5.3 (2.31)	-0.4 (2.44)
		95% CI	0.8, 9.9	-5.2, 4.3
		Difference from placebo		
		LS Mean (SE)	5.8 (3.35)	
		95% CI	-0.8, 12.3	
		p-value	0.0858	
		Corrected Hedges' g (95% CI)	0.26 (-0.04, 0.56)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	88 (45.8%)	81 (44.0%)
		LS Mean (SE)	1.8 (2.35)	-1.9 (2.44)
		95% CI	-2.9, 6.4	-6.7, 2.9
		Difference from placebo		
		LS Mean (SE)	3.7 (3.38)	
		95% CI	-3.0, 10.3	
		p-value	0.2797	
		Corrected Hedges' g (95% CI)	0.17 (-0.14, 0.47)	
Week 61	Change from Baseline	n (%)	78 (40.6%)	63 (34.2%)
		LS Mean (SE)	-1.8 (2.44)	3.4 (2.67)
		95% CI	-6.6, 3.0	-1.9, 8.6
		Difference from placebo		
		LS Mean (SE)	-5.2 (3.61)	
		95% CI	-12.3, 1.9	
		p-value	0.1516	
		Corrected Hedges' g (95% CI)	-0.24 (-0.57, 0.09)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	70 (38.0%)
		LS Mean (SE)	5.1 (2.43)	1.5 (2.57)
		95% CI	0.4, 9.9	-3.6, 6.5
		Difference from placebo		
		LS Mean (SE)	3.7 (3.54)	
		95% CI	-3.3, 10.6	
		p-value	0.3015	
		Corrected Hedges' g (95% CI)	0.17 (-0.15, 0.49)	
Week 73	Change from Baseline	n (%)	73 (38.0%)	61 (33.2%)
		LS Mean (SE)	-0.1 (2.51)	-3.4 (2.73)
		95% CI	-5.0, 4.8	-8.7, 2.0
		Difference from placebo		
		LS Mean (SE)	3.3 (3.70)	
		95% CI	-3.9, 10.6	
		p-value	0.3694	
		Corrected Hedges' g (95% CI)	0.15 (-0.19, 0.50)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	64 (33.3%)	56 (30.4%)
		LS Mean (SE)	-1.2 (2.63)	-2.5 (2.81)
		95% CI	-6.3, 4.0	-8.1, 3.0
		Difference from placebo		
		LS Mean (SE)	1.4 (3.85)	
		95% CI	-6.2, 8.9	
		p-value	0.7201	
		Corrected Hedges' g (95% CI)	0.07 (-0.29, 0.42)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	1.0 (2.60)	-1.9 (2.77)
		95% CI	-4.1, 6.1	-7.3, 3.6
		Difference from placebo		
		LS Mean (SE)	2.8 (3.80)	
		95% CI	-4.6, 10.3	
		p-value	0.4571	
		Corrected Hedges' g (95% CI)	0.13 (-0.22, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	54 (28.1%)	48 (26.1%)
		LS Mean (SE)	-2.8 (2.81)	-3.9 (2.98)
		95% CI	-8.3, 2.7	-9.7, 2.0
		Difference from placebo		
		LS Mean (SE)	1.0 (4.10)	
		95% CI	-7.0, 9.1	
		p-value	0.8005	
		Corrected Hedges' g (95% CI)	0.05 (-0.34, 0.44)	
Week 97	Change from Baseline	n (%)	62 (32.3%)	52 (28.3%)
		LS Mean (SE)	1.1 (2.69)	-1.8 (2.91)
		95% CI	-4.2, 6.4	-7.5, 3.9
		Difference from placebo		
		LS Mean (SE)	2.9 (3.98)	
		95% CI	-4.9, 10.7	
		p-value	0.4703	
		Corrected Hedges' g (95% CI)	0.14 (-0.23, 0.50)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	42 (22.8%)
		LS Mean (SE)	1.9 (2.83)	-0.8 (3.14)
		95% CI	-3.7, 7.4	-7.0, 5.4
		Difference from placebo		
		LS Mean (SE)	2.7 (4.23)	
		95% CI	-5.6, 11.0	
		p-value	0.5274	
		Corrected Hedges' g (95% CI)	0.13 (-0.27, 0.53)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	0.7 (2.92)	-3.5 (2.94)
		95% CI	-5.0, 6.4	-9.3, 2.3
		Difference from placebo		
		LS Mean (SE)	4.2 (4.16)	
		95% CI	-4.0, 12.3	
		p-value	0.3145	
		Corrected Hedges' g (95% CI)	0.20 (-0.19, 0.59)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	41 (22.3%)
		LS Mean (SE)	-3.3 (2.95)	-0.1 (3.18)
		95% CI	-9.1, 2.4	-6.3, 6.1
		Difference from placebo		
		LS Mean (SE)	-3.2 (4.33)	
		95% CI	-11.7, 5.3	
		p-value	0.4574	
		Corrected Hedges' g (95% CI)	-0.16 (-0.57, 0.26)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	49 (26.6%)
		LS Mean (SE)	1.9 (2.94)	0.6 (2.99)
		95% CI	-3.9, 7.6	-5.2, 6.5
		Difference from placebo		
		LS Mean (SE)	1.3 (4.20)	
		95% CI	-7.0, 9.5	
		p-value	0.7649	
		Corrected Hedges' g (95% CI)	0.06 (-0.33, 0.45)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	41 (22.3%)
		LS Mean (SE)	-2.0 (3.08)	-4.1 (3.19)
		95% CI	-8.1, 4.0	-10.4, 2.1
		Difference from placebo		
		LS Mean (SE)	2.1 (4.43)	
		95% CI	-6.6, 10.8	
		p-value	0.6336	
		Corrected Hedges' g (95% CI)	0.10 (-0.32, 0.53)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	42 (22.8%)
		LS Mean (SE)	1.9 (3.05)	-0.2 (3.17)
		95% CI	-4.1, 7.9	-6.4, 6.0
		Difference from placebo		
		LS Mean (SE)	2.1 (4.40)	
		95% CI	-6.5, 10.7	
		p-value	0.6329	
		Corrected Hedges' g (95% CI)	0.10 (-0.32, 0.52)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	-1.6 (3.07)	4.3 (3.38)
		95% CI	-7.6, 4.4	-2.3, 10.9
		Difference from placebo		
		LS Mean (SE)	-5.9 (4.56)	
		95% CI	-14.8, 3.1	
		p-value	0.1981	
		Corrected Hedges' g (95% CI)	-0.28 (-0.72, 0.16)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	30 (16.3%)
		LS Mean (SE)	-2.2 (3.31)	-0.2 (3.66)
		95% CI	-8.6, 4.3	-7.4, 7.0
		Difference from placebo		
		LS Mean (SE)	-2.0 (4.94)	
		95% CI	-11.6, 7.7	
		p-value	0.6918	
		Corrected Hedges' g (95% CI)	-0.10 (-0.58, 0.39)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	25 (13.6%)
		LS Mean (SE)	-1.6 (3.45)	2.9 (3.98)
		95% CI	-8.4, 5.2	-4.9, 10.7
		Difference from placebo		
		LS Mean (SE)	-4.4 (5.24)	
		95% CI	-14.7, 5.8	
		p-value	0.3962	
		Corrected Hedges' g (95% CI)	-0.22 (-0.73, 0.30)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	19 (10.3%)
		LS Mean (SE)	1.6 (3.88)	3.8 (4.51)
		95% CI	-6.0, 9.2	-5.0, 12.7
		Difference from placebo		
		LS Mean (SE)	-2.2 (5.94)	
		95% CI	-13.9, 9.4	
		p-value	0.7056	
		Corrected Hedges' g (95% CI)	-0.11 (-0.70, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	-3.6 (4.29)	1.3 (4.76)
		95% CI	-12.0, 4.8	-8.1, 10.6
		Difference from placebo		
		LS Mean (SE)	-4.8 (6.41)	
		95% CI	-17.4, 7.7	
		p-value	0.4502	
		Corrected Hedges' g (95% CI)	-0.24 (-0.88, 0.40)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	10 (5.4%)
		LS Mean (SE)	-3.8 (4.98)	8.9 (6.04)
		95% CI	-13.5, 6.0	-3.0, 20.7
		Difference from placebo		
		LS Mean (SE)	-12.6 (7.95)	
		95% CI	-28.2, 2.9	
		p-value	0.1117	
		Corrected Hedges' g (95% CI)	-0.61 (-1.41, 0.19)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	3.1 (5.75)	-12.7 (6.01)
		95% CI	-8.1, 14.4	-24.5, -0.9
		Difference from placebo		
		LS Mean (SE)	15.8 (8.52)	
		95% CI	-0.9, 32.5	
		p-value	0.0635	
		Corrected Hedges' g (95% CI)	0.77 (-0.08, 1.61)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	7 (3.8%)
		LS Mean (SE)	5.4 (6.98)	-9.8 (7.91)
		95% CI	-8.3, 19.1	-25.3, 5.8
		Difference from placebo		
		LS Mean (SE)	15.1 (11.29)	
		95% CI	-7.0, 37.3	
		p-value	0.1800	
		Corrected Hedges' g (95% CI)	0.68 (-0.33, 1.70)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	20.1 (10.14)	-7.8 (15.74)
		95% CI	0.2, 40.0	-38.7, 23.0
		Difference from placebo		
		LS Mean (SE)	27.9 (20.99)	
		95% CI	-13.2, 69.1	
		p-value	0.1834	
		Corrected Hedges' g (95% CI)	1.04 (-0.69, 2.77)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	172 (93.5%)
		LS Mean (SE)	31.5 (1.93)	24.0 (2.06)
		95% CI	27.7, 35.3	20.0, 28.1
		Difference from placebo		
		LS Mean (SE)	7.5 (2.81)	
		95% CI	2.0, 13.0	
		p-value	0.0078	
		Corrected Hedges' g (95% CI)	0.28 (0.07, 0.49)	
Week 4	Change from Baseline	n (%)	177 (92.2%)	170 (92.4%)
		LS Mean (SE)	18.4 (2.35)	13.1 (2.39)
		95% CI	13.8, 23.0	8.4, 17.8
		Difference from placebo		
		LS Mean (SE)	5.3 (3.35)	
		95% CI	-1.2, 11.9	
		p-value	0.1111	
		Corrected Hedges' g (95% CI)	0.17 (-0.04, 0.38)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	169 (88.0%)	161 (87.5%)
		LS Mean (SE)	26.0 (2.37)	19.5 (2.42)
		95% CI	21.4, 30.7	14.7, 24.3
		Difference from placebo		
		LS Mean (SE)	6.5 (3.39)	
		95% CI	-0.1, 13.2	
		p-value	0.0537	
		Corrected Hedges' g (95% CI)	0.21 (-0.00, 0.43)	
Week 10	Change from Baseline	n (%)	164 (85.4%)	151 (82.1%)
		LS Mean (SE)	30.8 (2.38)	23.3 (2.46)
		95% CI	26.1, 35.5	18.4, 28.1
		Difference from placebo		
		LS Mean (SE)	7.5 (3.43)	
		95% CI	0.8, 14.2	
		p-value	0.0286	
		Corrected Hedges' g (95% CI)	0.25 (0.02, 0.47)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	156 (81.3%)	144 (78.3%)
		LS Mean (SE)	36.2 (2.41)	28.6 (2.49)
		95% CI	31.4, 40.9	23.7, 33.4
		Difference from placebo		
		LS Mean (SE)	7.6 (3.47)	
		95% CI	0.8, 14.4	
		p-value	0.0284	
		Corrected Hedges' g (95% CI)	0.25 (0.03, 0.48)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	145 (78.8%)
		LS Mean (SE)	42.5 (2.43)	37.1 (2.49)
		95% CI	37.8, 47.3	32.2, 42.0
		Difference from placebo		
		LS Mean (SE)	5.5 (3.48)	
		95% CI	-1.4, 12.3	
		p-value	0.1165	
		Corrected Hedges' g (95% CI)	0.18 (-0.05, 0.41)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	146 (79.3%)
		LS Mean (SE)	47.5 (2.43)	37.4 (2.50)
		95% CI	42.8, 52.3	32.5, 42.3
		Difference from placebo		
		LS Mean (SE)	10.2 (3.49)	
		95% CI	3.3, 17.0	
		p-value	0.0036	
		Corrected Hedges' g (95% CI)	0.34 (0.11, 0.57)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	130 (70.7%)
		LS Mean (SE)	42.1 (2.50)	33.3 (2.57)
		95% CI	37.2, 47.0	28.3, 38.4
		Difference from placebo		
		LS Mean (SE)	8.8 (3.59)	
		95% CI	1.7, 15.8	
		p-value	0.0144	
		Corrected Hedges' g (95% CI)	0.30 (0.06, 0.54)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	126 (65.6%)	129 (70.1%)
		LS Mean (SE)	38.5 (2.57)	27.4 (2.59)
		95% CI	33.5, 43.6	22.3, 32.5
		Difference from placebo		
		LS Mean (SE)	11.1 (3.65)	
		95% CI	4.0, 18.3	
		p-value	0.0024	
		Corrected Hedges' g (95% CI)	0.38 (0.13, 0.63)	
Week 37	Change from Baseline	n (%)	113 (58.9%)	105 (57.1%)
		LS Mean (SE)	35.6 (2.65)	27.3 (2.74)
		95% CI	30.4, 40.8	21.9, 32.6
		Difference from placebo		
		LS Mean (SE)	8.4 (3.82)	
		95% CI	0.9, 15.9	
		p-value	0.0286	
		Corrected Hedges' g (95% CI)	0.30 (0.03, 0.56)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	106 (55.2%)	104 (56.5%)
		LS Mean (SE)	33.2 (2.71)	23.6 (2.78)
		95% CI	27.8, 38.5	18.1, 29.0
		Difference from placebo		
		LS Mean (SE)	9.6 (3.89)	
		95% CI	2.0, 17.2	
		p-value	0.0138	
		Corrected Hedges' g (95% CI)	0.34 (0.07, 0.61)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	81 (44.0%)
		LS Mean (SE)	34.0 (2.83)	24.0 (2.96)
		95% CI	28.5, 39.6	18.2, 29.8
		Difference from placebo		
		LS Mean (SE)	10.0 (4.11)	
		95% CI	2.0, 18.1	
		p-value	0.0146	
		Corrected Hedges' g (95% CI)	0.37 (0.07, 0.67)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	90 (46.9%)	82 (44.6%)
		LS Mean (SE)	28.4 (2.86)	23.4 (2.98)
		95% CI	22.8, 34.0	17.6, 29.3
		Difference from placebo		
		LS Mean (SE)	4.9 (4.14)	
		95% CI	-3.2, 13.1	
		p-value	0.2335	
		Corrected Hedges' g (95% CI)	0.18 (-0.12, 0.48)	
Week 61	Change from Baseline	n (%)	79 (41.1%)	64 (34.8%)
		LS Mean (SE)	35.2 (2.97)	20.7 (3.19)
		95% CI	29.3, 41.0	14.4, 27.0
		Difference from placebo		
		LS Mean (SE)	14.4 (4.38)	
		95% CI	5.9, 23.0	
		p-value	0.0010	
		Corrected Hedges' g (95% CI)	0.55 (0.22, 0.89)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	71 (38.6%)
		LS Mean (SE)	32.0 (2.96)	26.2 (3.11)
		95% CI	26.2, 37.9	20.1, 32.3
		Difference from placebo		
		LS Mean (SE)	5.8 (4.31)	
		95% CI	-2.6, 14.3	
		p-value	0.1777	
		Corrected Hedges' g (95% CI)	0.22 (-0.10, 0.54)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	60 (32.6%)
		LS Mean (SE)	29.3 (3.04)	18.7 (3.29)
		95% CI	23.3, 35.3	12.3, 25.2
		Difference from placebo		
		LS Mean (SE)	10.6 (4.50)	
		95% CI	1.8, 19.4	
		p-value	0.0187	
		Corrected Hedges' g (95% CI)	0.41 (0.06, 0.75)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	64 (33.3%)	56 (30.4%)
		LS Mean (SE)	28.2 (3.18)	22.1 (3.38)
		95% CI	21.9, 34.4	15.5, 28.8
		Difference from placebo		
		LS Mean (SE)	6.0 (4.66)	
		95% CI	-3.1, 15.2	
		p-value	0.1963	
		Corrected Hedges' g (95% CI)	0.24 (-0.12, 0.60)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	57 (31.0%)
		LS Mean (SE)	25.4 (3.16)	22.2 (3.38)
		95% CI	19.2, 31.6	15.6, 28.8
		Difference from placebo		
		LS Mean (SE)	3.2 (4.65)	
		95% CI	-5.9, 12.3	
		p-value	0.4929	
		Corrected Hedges' g (95% CI)	0.12 (-0.23, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	54 (28.1%)	48 (26.1%)
		LS Mean (SE)	23.9 (3.36)	22.0 (3.58)
		95% CI	17.3, 30.5	15.0, 29.1
		Difference from placebo		
		LS Mean (SE)	1.8 (4.92)	
		95% CI	-7.8, 11.5	
		p-value	0.7082	
		Corrected Hedges' g (95% CI)	0.07 (-0.32, 0.46)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	29.5 (3.24)	21.4 (3.51)
		95% CI	23.1, 35.8	14.5, 28.2
		Difference from placebo		
		LS Mean (SE)	8.1 (4.81)	
		95% CI	-1.3, 17.5	
		p-value	0.0914	
		Corrected Hedges' g (95% CI)	0.32 (-0.05, 0.69)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	42 (22.8%)
		LS Mean (SE)	28.7 (3.39)	24.2 (3.78)
		95% CI	22.0, 35.3	16.7, 31.6
		Difference from placebo		
		LS Mean (SE)	4.5 (5.11)	
		95% CI	-5.5, 14.6	
		p-value	0.3763	
		Corrected Hedges' g (95% CI)	0.18 (-0.22, 0.59)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	26.6 (3.47)	24.0 (3.57)
		95% CI	19.8, 33.4	17.0, 31.0
		Difference from placebo		
		LS Mean (SE)	2.6 (5.01)	
		95% CI	-7.2, 12.4	
		p-value	0.6052	
		Corrected Hedges' g (95% CI)	0.10 (-0.29, 0.49)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	41 (22.3%)
		LS Mean (SE)	29.1 (3.53)	22.6 (3.81)
		95% CI	22.2, 36.0	15.1, 30.0
		Difference from placebo		
		LS Mean (SE)	6.5 (5.22)	
		95% CI	-3.7, 16.8	
		p-value	0.2111	
		Corrected Hedges' g (95% CI)	0.26 (-0.15, 0.68)	
Week 121	Change from Baseline	n (%)	49 (25.5%)	50 (27.2%)
		LS Mean (SE)	32.1 (3.55)	22.7 (3.64)
		95% CI	25.2, 39.1	15.6, 29.8
		Difference from placebo		
		LS Mean (SE)	9.4 (5.14)	
		95% CI	-0.7, 19.5	
		p-value	0.0674	
		Corrected Hedges' g (95% CI)	0.37 (-0.03, 0.77)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	41 (22.3%)
		LS Mean (SE)	29.1 (3.68)	19.9 (3.82)
		95% CI	21.9, 36.3	12.5, 27.4
		Difference from placebo		
		LS Mean (SE)	9.2 (5.33)	
		95% CI	-1.3, 19.6	
		p-value	0.0854	
		Corrected Hedges' g (95% CI)	0.37 (-0.06, 0.80)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	42 (22.8%)
		LS Mean (SE)	29.5 (3.63)	26.4 (3.86)
		95% CI	22.4, 36.7	18.8, 34.0
		Difference from placebo		
		LS Mean (SE)	3.2 (5.35)	
		95% CI	-7.3, 13.6	
		p-value	0.5554	
		Corrected Hedges' g (95% CI)	0.13 (-0.29, 0.54)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	44 (22.9%)	36 (19.6%)
		LS Mean (SE)	26.8 (3.74)	26.5 (4.05)
		95% CI	19.5, 34.2	18.5, 34.4
		Difference from placebo		
		LS Mean (SE)	0.4 (5.57)	
		95% CI	-10.5, 11.3	
		p-value	0.9465	
		Corrected Hedges' g (95% CI)	0.02 (-0.43, 0.46)	
Week 145	Change from Baseline	n (%)	36 (18.8%)	30 (16.3%)
		LS Mean (SE)	30.7 (3.97)	26.1 (4.46)
		95% CI	22.9, 38.5	17.4, 34.9
		Difference from placebo		
		LS Mean (SE)	4.6 (6.03)	
		95% CI	-7.2, 16.4	
		p-value	0.4461	
		Corrected Hedges' g (95% CI)	0.19 (-0.30, 0.67)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	25 (13.6%)
		LS Mean (SE)	32.3 (4.08)	25.5 (4.83)
		95% CI	24.3, 40.3	16.0, 35.0
		Difference from placebo		
		LS Mean (SE)	6.8 (6.44)	
		95% CI	-5.8, 19.5	
		p-value	0.2878	
		Corrected Hedges' g (95% CI)	0.28 (-0.24, 0.80)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	19 (10.3%)
		LS Mean (SE)	33.6 (4.60)	27.8 (5.46)
		95% CI	24.6, 42.6	17.1, 38.5
		Difference from placebo		
		LS Mean (SE)	5.8 (6.99)	
		95% CI	-7.9, 19.5	
		p-value	0.4044	
		Corrected Hedges' g (95% CI)	0.24 (-0.35, 0.84)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	28.9 (5.01)	8.7 (5.88)
		95% CI	19.1, 38.8	-2.9, 20.2
		Difference from placebo		
		LS Mean (SE)	20.3 (7.64)	
		95% CI	5.3, 35.2	
		p-value	0.0080	
		Corrected Hedges' g (95% CI)	0.84 (0.18, 1.51)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	10 (5.4%)
		LS Mean (SE)	32.2 (5.54)	30.9 (7.38)
		95% CI	21.4, 43.1	16.5, 45.4
		Difference from placebo		
		LS Mean (SE)	1.3 (9.27)	
		95% CI	-16.9, 19.4	
		p-value	0.8900	
		Corrected Hedges' g (95% CI)	0.05 (-0.73, 0.84)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	38.1 (8.46)	26.8 (10.14)
		95% CI	21.5, 54.7	6.9, 46.6
		Difference from placebo		
		LS Mean (SE)	11.3 (9.66)	
		95% CI	-7.6, 30.3	
		p-value	0.2411	
		Corrected Hedges' g (95% CI)	0.35 (-0.48, 1.17)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	7 (3.8%)
		LS Mean (SE)	25.4 (7.75)	19.5 (8.55)
		95% CI	10.2, 40.6	2.7, 36.3
		Difference from placebo		
		LS Mean (SE)	5.9 (11.74)	
		95% CI	-17.1, 28.9	
		p-value	0.6141	
		Corrected Hedges' g (95% CI)	0.24 (-0.75, 1.23)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	31.4 (10.69)	13.6 (15.51)
		95% CI	10.5, 52.4	-16.8, 44.0
		Difference from placebo		
		LS Mean (SE)	17.8 (19.44)	
		95% CI	-20.3, 55.9	
		p-value	0.3596	
		Corrected Hedges' g (95% CI)	0.64 (-1.04, 2.31)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	172 (93.5%)
		LS Mean (SE)	15.3 (1.46)	10.7 (1.59)
		95% CI	12.4, 18.2	7.5, 13.8
		Difference from placebo		
		LS Mean (SE)	4.6 (2.17)	
		95% CI	0.4, 8.9	
		p-value	0.0325	
		Corrected Hedges' g (95% CI)	0.23 (0.02, 0.44)	
Week 4	Change from Baseline	n (%)	177 (92.2%)	170 (92.4%)
		LS Mean (SE)	9.2 (1.98)	8.0 (2.02)
		95% CI	5.3, 13.0	4.0, 11.9
		Difference from placebo		
		LS Mean (SE)	1.2 (2.83)	
		95% CI	-4.4, 6.8	
		p-value	0.6720	
		Corrected Hedges' g (95% CI)	0.05 (-0.17, 0.26)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	168 (87.5%)	161 (87.5%)
		LS Mean (SE)	11.9 (2.01)	11.1 (2.05)
		95% CI	7.9, 15.8	7.0, 15.1
		Difference from placebo		
		LS Mean (SE)	0.8 (2.88)	
		95% CI	-4.8, 6.5	
		p-value	0.7807	
		Corrected Hedges' g (95% CI)	0.03 (-0.19, 0.25)	
Week 10	Change from Baseline	n (%)	164 (85.4%)	151 (82.1%)
		LS Mean (SE)	11.3 (2.02)	12.3 (2.11)
		95% CI	7.3, 15.3	8.2, 16.4
		Difference from placebo		
		LS Mean (SE)	-1.0 (2.93)	
		95% CI	-6.7, 4.7	
		p-value	0.7314	
		Corrected Hedges' g (95% CI)	-0.04 (-0.26, 0.18)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	144 (78.3%)
		LS Mean (SE)	14.4 (2.06)	12.1 (2.13)
		95% CI	10.3, 18.4	7.9, 16.3
		Difference from placebo		
		LS Mean (SE)	2.3 (2.97)	
		95% CI	-3.5, 8.1	
		p-value	0.4426	
		Corrected Hedges' g (95% CI)	0.09 (-0.14, 0.31)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	145 (78.8%)
		LS Mean (SE)	17.0 (2.09)	14.4 (2.13)
		95% CI	12.9, 21.1	10.2, 18.5
		Difference from placebo		
		LS Mean (SE)	2.7 (2.99)	
		95% CI	-3.2, 8.5	
		p-value	0.3730	
		Corrected Hedges' g (95% CI)	0.10 (-0.12, 0.33)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	152 (79.2%)	146 (79.3%)
		LS Mean (SE)	12.3 (2.09)	10.8 (2.13)
		95% CI	8.3, 16.4	6.7, 15.0
		Difference from placebo		
		LS Mean (SE)	1.5 (2.99)	
		95% CI	-4.3, 7.4	
		p-value	0.6121	
		Corrected Hedges' g (95% CI)	0.06 (-0.17, 0.29)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	130 (70.7%)
		LS Mean (SE)	14.5 (2.15)	11.6 (2.22)
		95% CI	10.3, 18.7	7.3, 16.0
		Difference from placebo		
		LS Mean (SE)	2.9 (3.09)	
		95% CI	-3.2, 9.0	
		p-value	0.3520	
		Corrected Hedges' g (95% CI)	0.11 (-0.13, 0.35)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	127 (66.1%)	129 (70.1%)
		LS Mean (SE)	13.2 (2.23)	11.3 (2.24)
		95% CI	8.9, 17.6	6.9, 15.7
		Difference from placebo		
		LS Mean (SE)	1.9 (3.17)	
		95% CI	-4.3, 8.1	
		p-value	0.5429	
		Corrected Hedges' g (95% CI)	0.08 (-0.17, 0.32)	
Week 37	Change from Baseline	n (%)	112 (58.3%)	105 (57.1%)
		LS Mean (SE)	10.5 (2.33)	11.5 (2.40)
		95% CI	5.9, 15.0	6.7, 16.2
		Difference from placebo		
		LS Mean (SE)	-1.0 (3.36)	
		95% CI	-7.6, 5.6	
		p-value	0.7714	
		Corrected Hedges' g (95% CI)	-0.04 (-0.31, 0.23)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	106 (55.2%)	104 (56.5%)
		LS Mean (SE)	17.6 (2.39)	8.1 (2.43)
		95% CI	13.0, 22.3	3.4, 12.9
		Difference from placebo		
		LS Mean (SE)	9.5 (3.43)	
		95% CI	2.8, 16.2	
		p-value	0.0055	
		Corrected Hedges' g (95% CI)	0.38 (0.11, 0.66)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	81 (44.0%)
		LS Mean (SE)	16.4 (2.51)	9.2 (2.64)
		95% CI	11.4, 21.3	4.0, 14.4
		Difference from placebo		
		LS Mean (SE)	7.2 (3.66)	
		95% CI	-0.0, 14.3	
		p-value	0.0506	
		Corrected Hedges' g (95% CI)	0.30 (-0.00, 0.60)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	90 (46.9%)	80 (43.5%)
		LS Mean (SE)	16.8 (2.54)	16.2 (2.67)
		95% CI	11.8, 21.8	10.9, 21.4
		Difference from placebo		
		LS Mean (SE)	0.6 (3.70)	
		95% CI	-6.6, 7.9	
		p-value	0.8654	
		Corrected Hedges' g (95% CI)	0.03 (-0.28, 0.33)	
Week 61	Change from Baseline	n (%)	79 (41.1%)	64 (34.8%)
		LS Mean (SE)	17.4 (2.66)	9.5 (2.90)
		95% CI	12.2, 22.6	3.9, 15.2
		Difference from placebo		
		LS Mean (SE)	7.9 (3.95)	
		95% CI	0.1, 15.6	
		p-value	0.0459	
		Corrected Hedges' g (95% CI)	0.33 (0.00, 0.67)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	71 (38.6%)
		LS Mean (SE)	16.1 (2.65)	12.2 (2.80)
		95% CI	10.9, 21.3	6.7, 17.7
		Difference from placebo		
		LS Mean (SE)	3.9 (3.87)	
		95% CI	-3.7, 11.4	
		p-value	0.3191	
		Corrected Hedges' g (95% CI)	0.16 (-0.16, 0.48)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	61 (33.2%)
		LS Mean (SE)	12.4 (2.73)	11.6 (2.98)
		95% CI	7.0, 17.7	5.8, 17.5
		Difference from placebo		
		LS Mean (SE)	0.7 (4.05)	
		95% CI	-7.2, 8.7	
		p-value	0.8533	
		Corrected Hedges' g (95% CI)	0.03 (-0.31, 0.37)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	64 (33.3%)	56 (30.4%)
		LS Mean (SE)	10.8 (2.89)	5.7 (3.07)
		95% CI	5.2, 16.5	-0.3, 11.7
		Difference from placebo		
		LS Mean (SE)	5.1 (4.23)	
		95% CI	-3.2, 13.4	
		p-value	0.2249	
		Corrected Hedges' g (95% CI)	0.22 (-0.14, 0.58)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	19.1 (2.84)	9.7 (3.05)
		95% CI	13.5, 24.7	3.7, 15.7
		Difference from placebo		
		LS Mean (SE)	9.4 (4.19)	
		95% CI	1.2, 17.6	
		p-value	0.0248	
		Corrected Hedges' g (95% CI)	0.40 (0.05, 0.75)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	54 (28.1%)	48 (26.1%)
		LS Mean (SE)	11.4 (3.09)	10.0 (3.28)
		95% CI	5.4, 17.5	3.6, 16.5
		Difference from placebo		
		LS Mean (SE)	1.4 (4.50)	
		95% CI	-7.4, 10.2	
		p-value	0.7588	
		Corrected Hedges' g (95% CI)	0.06 (-0.33, 0.45)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	17.7 (2.92)	8.7 (3.21)
		95% CI	11.9, 23.4	2.4, 14.9
		Difference from placebo		
		LS Mean (SE)	9.0 (4.35)	
		95% CI	0.5, 17.5	
		p-value	0.0385	
		Corrected Hedges' g (95% CI)	0.39 (0.02, 0.76)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	42 (22.8%)
		LS Mean (SE)	13.4 (3.10)	13.0 (3.47)
		95% CI	7.3, 19.5	6.2, 19.8
		Difference from placebo		
		LS Mean (SE)	0.4 (4.67)	
		95% CI	-8.7, 9.6	
		p-value	0.9294	
		Corrected Hedges' g (95% CI)	0.02 (-0.39, 0.42)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	15.6 (3.18)	12.7 (3.24)
		95% CI	9.3, 21.8	6.4, 19.1
		Difference from placebo		
		LS Mean (SE)	2.8 (4.57)	
		95% CI	-6.1, 11.8	
		p-value	0.5329	
		Corrected Hedges' g (95% CI)	0.12 (-0.27, 0.51)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	41 (22.3%)
		LS Mean (SE)	9.1 (3.24)	8.0 (3.51)
		95% CI	2.8, 15.5	1.1, 14.9
		Difference from placebo		
		LS Mean (SE)	1.1 (4.79)	
		95% CI	-8.3, 10.5	
		p-value	0.8139	
		Corrected Hedges' g (95% CI)	0.05 (-0.37, 0.46)	
Week 121	Change from Baseline	n (%)	49 (25.5%)	50 (27.2%)
		LS Mean (SE)	11.1 (3.24)	9.4 (3.30)
		95% CI	4.7, 17.4	2.9, 15.9
		Difference from placebo		
		LS Mean (SE)	1.7 (4.64)	
		95% CI	-7.4, 10.8	
		p-value	0.7160	
		Corrected Hedges' g (95% CI)	0.07 (-0.32, 0.47)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	41 (22.3%)
		LS Mean (SE)	12.5 (3.39)	10.7 (3.51)
		95% CI	5.8, 19.1	3.8, 17.6
		Difference from placebo		
		LS Mean (SE)	1.8 (4.89)	
		95% CI	-7.8, 11.3	
		p-value	0.7197	
		Corrected Hedges' g (95% CI)	0.08 (-0.35, 0.50)	
Week 133	Change from Baseline	n (%)	45 (23.4%)	42 (22.8%)
		LS Mean (SE)	16.6 (3.37)	10.6 (3.56)
		95% CI	10.0, 23.2	3.6, 17.6
		Difference from placebo		
		LS Mean (SE)	6.0 (4.89)	
		95% CI	-3.6, 15.6	
		p-value	0.2198	
		Corrected Hedges' g (95% CI)	0.26 (-0.16, 0.68)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	9.9 (3.37)	5.6 (3.72)
		95% CI	3.2, 16.5	-1.7, 12.9
		Difference from placebo		
		LS Mean (SE)	4.3 (5.03)	
		95% CI	-5.6, 14.1	
		p-value	0.3965	
		Corrected Hedges' g (95% CI)	0.19 (-0.25, 0.63)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	30 (16.3%)
		LS Mean (SE)	11.5 (3.66)	7.5 (4.09)
		95% CI	4.4, 18.7	-0.6, 15.5
		Difference from placebo		
		LS Mean (SE)	4.1 (5.52)	
		95% CI	-6.7, 14.9	
		p-value	0.4594	
		Corrected Hedges' g (95% CI)	0.18 (-0.30, 0.66)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	25 (13.6%)
		LS Mean (SE)	13.2 (3.77)	7.6 (4.40)
		95% CI	5.8, 20.6	-1.1, 16.2
		Difference from placebo		
		LS Mean (SE)	5.6 (5.80)	
		95% CI	-5.7, 17.0	
		p-value	0.3321	
		Corrected Hedges' g (95% CI)	0.25 (-0.26, 0.77)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	19 (10.3%)
		LS Mean (SE)	17.4 (4.36)	10.0 (5.22)
		95% CI	8.9, 26.0	-0.3, 20.2
		Difference from placebo		
		LS Mean (SE)	7.4 (6.61)	
		95% CI	-5.5, 20.4	
		p-value	0.2603	
		Corrected Hedges' g (95% CI)	0.33 (-0.27, 0.92)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	15.4 (4.78)	12.0 (5.35)
		95% CI	6.1, 24.8	1.6, 22.5
		Difference from placebo		
		LS Mean (SE)	3.4 (7.09)	
		95% CI	-10.5, 17.3	
		p-value	0.6319	
		Corrected Hedges' g (95% CI)	0.15 (-0.49, 0.79)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	10 (5.4%)
		LS Mean (SE)	23.4 (5.31)	17.0 (6.70)
		95% CI	13.0, 33.8	3.9, 30.2
		Difference from placebo		
		LS Mean (SE)	6.4 (8.50)	
		95% CI	-10.3, 23.0	
		p-value	0.4540	
		Corrected Hedges' g (95% CI)	0.29 (-0.50, 1.07)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	23.9 (6.25)	5.9 (6.55)
		95% CI	11.6, 36.1	-6.9, 18.8
		Difference from placebo		
		LS Mean (SE)	17.9 (9.01)	
		95% CI	0.3, 35.6	
		p-value	0.0466	
		Corrected Hedges' g (95% CI)	0.80 (-0.05, 1.65)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	7 (3.8%)
		LS Mean (SE)	19.4 (7.22)	3.5 (8.80)
		95% CI	5.2, 33.5	-13.8, 20.7
		Difference from placebo		
		LS Mean (SE)	15.9 (11.59)	
		95% CI	-6.8, 38.6	
		p-value	0.1702	
		Corrected Hedges' g (95% CI)	0.67 (-0.34, 1.69)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	38.1 (10.35)	24.8 (15.98)
		95% CI	17.8, 58.4	-6.5, 56.2
		Difference from placebo		
		LS Mean (SE)	13.2 (20.25)	
		95% CI	-26.5, 52.9	
		p-value	0.5131	
		Corrected Hedges' g (95% CI)	0.48 (-1.18, 2.14)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	180 (93.8%)	172 (93.5%)
		LS Mean (SE)	23.1 (1.60)	21.4 (1.71)
		95% CI	20.0, 26.3	18.0, 24.7
		Difference from placebo		
		LS Mean (SE)	1.7 (2.34)	
		95% CI	-2.9, 6.4	
		p-value	0.4562	
		Corrected Hedges' g (95% CI)	0.08 (-0.13, 0.29)	
Week 4	Change from Baseline	n (%)	175 (91.1%)	169 (91.8%)
		LS Mean (SE)	81.4 (2.47)	74.9 (2.52)
		95% CI	76.5, 86.3	70.0, 79.9
		Difference from placebo		
		LS Mean (SE)	6.5 (3.53)	
		95% CI	-0.5, 13.4	
		p-value	0.0674	
		Corrected Hedges' g (95% CI)	0.20 (-0.01, 0.41)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	166 (86.5%)	161 (87.5%)
		LS Mean (SE)	77.9 (2.51)	72.0 (2.56)
		95% CI	72.9, 82.8	67.0, 77.0
		Difference from placebo		
		LS Mean (SE)	5.9 (3.59)	
		95% CI	-1.2, 12.9	
		p-value	0.1021	
		Corrected Hedges' g (95% CI)	0.18 (-0.04, 0.40)	
Week 10	Change from Baseline	n (%)	163 (84.9%)	151 (82.1%)
		LS Mean (SE)	70.1 (2.53)	68.6 (2.62)
		95% CI	65.2, 75.1	63.4, 73.7
		Difference from placebo		
		LS Mean (SE)	1.5 (3.64)	
		95% CI	-5.6, 8.7	
		p-value	0.6716	
		Corrected Hedges' g (95% CI)	0.05 (-0.17, 0.27)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	153 (79.7%)	142 (77.2%)
		LS Mean (SE)	67.6 (2.59)	69.7 (2.68)
		95% CI	62.5, 72.6	64.5, 75.0
		Difference from placebo		
		LS Mean (SE)	-2.1 (3.72)	
		95% CI	-9.4, 5.2	
		p-value	0.5648	
		Corrected Hedges' g (95% CI)	-0.07 (-0.30, 0.16)	
Week 16	Change from Baseline	n (%)	150 (78.1%)	145 (78.8%)
		LS Mean (SE)	66.5 (2.61)	66.8 (2.67)
		95% CI	61.4, 71.7	61.6, 72.0
		Difference from placebo		
		LS Mean (SE)	-0.3 (3.74)	
		95% CI	-7.6, 7.1	
		p-value	0.9429	
		Corrected Hedges' g (95% CI)	-0.01 (-0.24, 0.22)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	149 (77.6%)	145 (78.8%)
		LS Mean (SE)	60.1 (2.62)	64.9 (2.68)
		95% CI	54.9, 65.2	59.6, 70.1
		Difference from placebo		
		LS Mean (SE)	-4.8 (3.75)	
		95% CI	-12.2, 2.5	
		p-value	0.1989	
		Corrected Hedges' g (95% CI)	-0.15 (-0.38, 0.08)	
Week 25	Change from Baseline	n (%)	137 (71.4%)	129 (70.1%)
		LS Mean (SE)	41.0 (2.71)	42.3 (2.81)
		95% CI	35.7, 46.3	36.8, 47.9
		Difference from placebo		
		LS Mean (SE)	-1.3 (3.91)	
		95% CI	-9.0, 6.3	
		p-value	0.7341	
		Corrected Hedges' g (95% CI)	-0.04 (-0.28, 0.20)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	126 (65.6%)	126 (68.5%)
		LS Mean (SE)	20.9 (2.81)	22.7 (2.85)
		95% CI	15.3, 26.4	17.2, 28.3
		Difference from placebo		
		LS Mean (SE)	-1.9 (4.01)	
		95% CI	-9.8, 6.0	
		p-value	0.6381	
		Corrected Hedges' g (95% CI)	-0.06 (-0.31, 0.19)	
Week 37	Change from Baseline	n (%)	111 (57.8%)	104 (56.5%)
		LS Mean (SE)	12.3 (2.96)	14.4 (3.07)
		95% CI	6.5, 18.1	8.4, 20.4
		Difference from placebo		
		LS Mean (SE)	-2.1 (4.27)	
		95% CI	-10.5, 6.3	
		p-value	0.6218	
		Corrected Hedges' g (95% CI)	-0.07 (-0.33, 0.20)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	104 (54.2%)	103 (56.0%)
		LS Mean (SE)	13.8 (3.05)	7.3 (3.10)
		95% CI	7.8, 19.8	1.2, 13.4
		Difference from placebo		
		LS Mean (SE)	6.5 (4.36)	
		95% CI	-2.1, 15.0	
		p-value	0.1366	
		Corrected Hedges' g (95% CI)	0.21 (-0.07, 0.48)	
Week 49	Change from Baseline	n (%)	91 (47.4%)	81 (44.0%)
		LS Mean (SE)	8.7 (3.21)	4.7 (3.39)
		95% CI	2.4, 15.0	-2.0, 11.3
		Difference from placebo		
		LS Mean (SE)	4.1 (4.67)	
		95% CI	-5.1, 13.2	
		p-value	0.3841	
		Corrected Hedges' g (95% CI)	0.13 (-0.17, 0.43)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	89 (46.4%)	81 (44.0%)
		LS Mean (SE)	8.0 (3.26)	6.8 (3.41)
		95% CI	1.6, 14.4	0.1, 13.5
		Difference from placebo		
		LS Mean (SE)	1.2 (4.71)	
		95% CI	-8.1, 10.4	
		p-value	0.8010	
		Corrected Hedges' g (95% CI)	0.04 (-0.26, 0.34)	
Week 61	Change from Baseline	n (%)	79 (41.1%)	64 (34.8%)
		LS Mean (SE)	9.7 (3.41)	9.7 (3.73)
		95% CI	3.0, 16.3	2.4, 17.0
		Difference from placebo		
		LS Mean (SE)	0.0 (5.07)	
		95% CI	-9.9, 9.9	
		p-value	0.9993	
		Corrected Hedges' g (95% CI)	0.00 (-0.33, 0.33)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	71 (38.6%)
		LS Mean (SE)	7.1 (3.40)	9.2 (3.60)
		95% CI	0.4, 13.7	2.1, 16.2
		Difference from placebo		
		LS Mean (SE)	-2.1 (4.95)	
		95% CI	-11.8, 7.6	
		p-value	0.6708	
		Corrected Hedges' g (95% CI)	-0.07 (-0.39, 0.25)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	61 (33.2%)
		LS Mean (SE)	13.0 (3.53)	6.8 (3.84)
		95% CI	6.1, 19.9	-0.8, 14.3
		Difference from placebo		
		LS Mean (SE)	6.2 (5.23)	
		95% CI	-4.0, 16.5	
		p-value	0.2341	
		Corrected Hedges' g (95% CI)	0.21 (-0.13, 0.55)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	63 (32.8%)	55 (29.9%)
		LS Mean (SE)	5.9 (3.75)	9.1 (4.01)
		95% CI	-1.5, 13.2	1.2, 17.0
		Difference from placebo		
		LS Mean (SE)	-3.2 (5.50)	
		95% CI	-14.0, 7.5	
		p-value	0.5552	
		Corrected Hedges' g (95% CI)	-0.11 (-0.47, 0.25)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	10.8 (3.69)	8.7 (3.94)
		95% CI	3.6, 18.1	0.9, 16.4
		Difference from placebo		
		LS Mean (SE)	2.1 (5.40)	
		95% CI	-8.4, 12.7	
		p-value	0.6912	
		Corrected Hedges' g (95% CI)	0.07 (-0.28, 0.42)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	54 (28.1%)	48 (26.1%)
		LS Mean (SE)	6.1 (4.00)	5.4 (4.28)
		95% CI	-1.8, 13.9	-3.0, 13.7
		Difference from placebo		
		LS Mean (SE)	0.7 (5.86)	
		95% CI	-10.8, 12.2	
		p-value	0.9046	
		Corrected Hedges' g (95% CI)	0.02 (-0.37, 0.41)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	9.5 (3.80)	9.2 (4.16)
		95% CI	2.1, 16.9	1.0, 17.4
		Difference from placebo		
		LS Mean (SE)	0.3 (5.64)	
		95% CI	-10.8, 11.3	
		p-value	0.9586	
		Corrected Hedges' g (95% CI)	0.01 (-0.36, 0.38)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	42 (22.8%)
		LS Mean (SE)	9.5 (4.06)	8.1 (4.53)
		95% CI	1.5, 17.5	-0.8, 17.0
		Difference from placebo		
		LS Mean (SE)	1.4 (6.13)	
		95% CI	-10.6, 13.4	
		p-value	0.8185	
		Corrected Hedges' g (95% CI)	0.05 (-0.36, 0.45)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	8.3 (4.14)	8.4 (4.22)
		95% CI	0.2, 16.4	0.1, 16.6
		Difference from placebo		
		LS Mean (SE)	-0.1 (5.92)	
		95% CI	-11.7, 11.5	
		p-value	0.9906	
		Corrected Hedges' g (95% CI)	-0.00 (-0.39, 0.39)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	41 (22.3%)
		LS Mean (SE)	10.2 (4.26)	13.6 (4.56)
		95% CI	1.9, 18.6	4.7, 22.5
		Difference from placebo		
		LS Mean (SE)	-3.3 (6.26)	
		95% CI	-15.6, 8.9	
		p-value	0.5931	
		Corrected Hedges' g (95% CI)	-0.11 (-0.53, 0.30)	
Week 121	Change from Baseline	n (%)	49 (25.5%)	50 (27.2%)
		LS Mean (SE)	6.7 (4.24)	11.4 (4.28)
		95% CI	-1.6, 15.0	3.0, 19.8
		Difference from placebo		
		LS Mean (SE)	-4.8 (6.05)	
		95% CI	-16.6, 7.1	
		p-value	0.4296	
		Corrected Hedges' g (95% CI)	-0.16 (-0.55, 0.24)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	41 (22.3%)
		LS Mean (SE)	9.2 (4.47)	13.1 (4.59)
		95% CI	0.4, 17.9	4.1, 22.1
		Difference from placebo		
		LS Mean (SE)	-4.0 (6.39)	
		95% CI	-16.5, 8.6	
		p-value	0.5337	
		Corrected Hedges' g (95% CI)	-0.13 (-0.56, 0.29)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	42 (22.8%)
		LS Mean (SE)	10.3 (4.38)	13.1 (4.57)
		95% CI	1.8, 18.9	4.1, 22.0
		Difference from placebo		
		LS Mean (SE)	-2.7 (6.33)	
		95% CI	-15.1, 9.7	
		p-value	0.6653	
		Corrected Hedges' g (95% CI)	-0.09 (-0.51, 0.33)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	7.2 (4.47)	7.3 (4.90)
		95% CI	-1.6, 16.0	-2.4, 16.9
		Difference from placebo		
		LS Mean (SE)	-0.1 (6.66)	
		95% CI	-13.1, 13.0	
		p-value	0.9921	
		Corrected Hedges' g (95% CI)	-0.00 (-0.44, 0.44)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	30 (16.3%)
		LS Mean (SE)	15.6 (4.85)	10.8 (5.33)
		95% CI	6.1, 25.1	0.3, 21.2
		Difference from placebo		
		LS Mean (SE)	4.9 (7.22)	
		95% CI	-9.3, 19.0	
		p-value	0.5014	
		Corrected Hedges' g (95% CI)	0.16 (-0.32, 0.65)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	25 (13.6%)
		LS Mean (SE)	15.3 (5.13)	8.1 (5.82)
		95% CI	5.2, 25.4	-3.3, 19.5
		Difference from placebo		
		LS Mean (SE)	7.2 (7.76)	
		95% CI	-8.0, 22.4	
		p-value	0.3547	
		Corrected Hedges' g (95% CI)	0.24 (-0.28, 0.75)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	19 (10.3%)
		LS Mean (SE)	12.7 (5.74)	5.6 (6.66)
		95% CI	1.4, 23.9	-7.4, 18.7
		Difference from placebo		
		LS Mean (SE)	7.0 (8.88)	
		95% CI	-10.4, 24.4	
		p-value	0.4280	
		Corrected Hedges' g (95% CI)	0.24 (-0.36, 0.83)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	17 (9.2%)
		LS Mean (SE)	15.7 (6.30)	7.8 (7.12)
		95% CI	3.4, 28.1	-6.2, 21.8
		Difference from placebo		
		LS Mean (SE)	7.9 (9.54)	
		95% CI	-10.8, 26.6	
		p-value	0.4055	
		Corrected Hedges' g (95% CI)	0.27 (-0.38, 0.91)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	10 (5.4%)
		LS Mean (SE)	15.9 (7.09)	12.0 (8.91)
		95% CI	2.0, 29.8	-5.4, 29.5
		Difference from placebo		
		LS Mean (SE)	3.8 (11.42)	
		95% CI	-18.6, 26.2	
		p-value	0.7373	
		Corrected Hedges' g (95% CI)	0.13 (-0.65, 0.91)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	17.9 (8.44)	8.8 (8.75)
		95% CI	1.3, 34.4	-8.3, 26.0
		Difference from placebo		
		LS Mean (SE)	9.1 (12.13)	
		95% CI	-14.7, 32.8	
		p-value	0.4550	
		Corrected Hedges' g (95% CI)	0.30 (-0.52, 1.12)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	7 (3.8%)
		LS Mean (SE)	18.2 (10.04)	4.0 (10.94)
		95% CI	-1.5, 37.9	-17.4, 25.5
		Difference from placebo		
		LS Mean (SE)	14.2 (14.83)	
		95% CI	-14.9, 43.3	
		p-value	0.3382	
		Corrected Hedges' g (95% CI)	0.45 (-0.55, 1.45)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	181 (94.3%)	172 (93.5%)
		LS Mean (SE)	13.8 (1.51)	9.9 (1.60)
		95% CI	10.8, 16.7	6.7, 13.0
		Difference from placebo		
		LS Mean (SE)	3.9 (2.20)	
		95% CI	-0.4, 8.2	
		p-value	0.0780	
		Corrected Hedges' g (95% CI)	0.19 (-0.02, 0.40)	
Week 4	Change from Baseline	n (%)	177 (92.2%)	170 (92.4%)
		LS Mean (SE)	19.3 (1.99)	13.8 (2.04)
		95% CI	15.4, 23.2	9.8, 17.8
		Difference from placebo		
		LS Mean (SE)	5.5 (2.85)	
		95% CI	-0.1, 11.1	
		p-value	0.0544	
		Corrected Hedges' g (95% CI)	0.21 (-0.00, 0.42)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.
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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	169 (88.0%)	161 (87.5%)
		LS Mean (SE)	25.0 (2.01)	19.3 (2.06)
		95% CI	21.1, 29.0	15.3, 23.4
		Difference from placebo		
		LS Mean (SE)	5.7 (2.88)	
		95% CI	0.1, 11.4	
		p-value	0.0478	
		Corrected Hedges' g (95% CI)	0.22 (0.00, 0.43)	
Week 10	Change from Baseline	n (%)	164 (85.4%)	152 (82.6%)
		LS Mean (SE)	24.8 (2.03)	20.2 (2.10)
		95% CI	20.9, 28.8	16.0, 24.3
		Difference from placebo		
		LS Mean (SE)	4.7 (2.92)	
		95% CI	-1.0, 10.4	
		p-value	0.1089	
		Corrected Hedges' g (95% CI)	0.18 (-0.04, 0.40)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	157 (81.8%)	144 (78.3%)
		LS Mean (SE)	26.2 (2.05)	21.3 (2.13)
		95% CI	22.2, 30.2	17.1, 25.4
		Difference from placebo		
		LS Mean (SE)	5.0 (2.96)	
		95% CI	-0.8, 10.8	
		p-value	0.0942	
		Corrected Hedges' g (95% CI)	0.19 (-0.03, 0.42)	
Week 16	Change from Baseline	n (%)	152 (79.2%)	146 (79.3%)
		LS Mean (SE)	27.9 (2.07)	23.0 (2.13)
		95% CI	23.8, 32.0	18.8, 27.2
		Difference from placebo		
		LS Mean (SE)	4.9 (2.97)	
		95% CI	-1.0, 10.7	
		p-value	0.1017	
		Corrected Hedges' g (95% CI)	0.19 (-0.04, 0.42)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	146 (79.3%)
		LS Mean (SE)	24.9 (2.08)	15.2 (2.14)
		95% CI	20.8, 29.0	11.0, 19.4
		Difference from placebo		
		LS Mean (SE)	9.7 (2.98)	
		95% CI	3.9, 15.6	
		p-value	0.0012	
		Corrected Hedges' g (95% CI)	0.38 (0.15, 0.60)	
Week 25	Change from Baseline	n (%)	138 (71.9%)	129 (70.1%)
		LS Mean (SE)	15.2 (2.14)	7.8 (2.21)
		95% CI	11.0, 19.4	3.4, 12.1
		Difference from placebo		
		LS Mean (SE)	7.5 (3.08)	
		95% CI	1.4, 13.5	
		p-value	0.0154	
		Corrected Hedges' g (95% CI)	0.30 (0.06, 0.54)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	127 (66.1%)	129 (70.1%)
		LS Mean (SE)	10.4 (2.21)	7.9 (2.24)
		95% CI	6.1, 14.7	3.5, 12.3
		Difference from placebo		
		LS Mean (SE)	2.5 (3.14)	
		95% CI	-3.7, 8.7	
		p-value	0.4241	
		Corrected Hedges' g (95% CI)	0.10 (-0.15, 0.34)	
Week 37	Change from Baseline	n (%)	113 (58.9%)	105 (57.1%)
		LS Mean (SE)	9.7 (2.29)	6.1 (2.37)
		95% CI	5.2, 14.2	1.4, 10.7
		Difference from placebo		
		LS Mean (SE)	3.6 (3.30)	
		95% CI	-2.9, 10.1	
		p-value	0.2744	
		Corrected Hedges' g (95% CI)	0.15 (-0.12, 0.41)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	106 (55.2%)	104 (56.5%)
		LS Mean (SE)	10.2 (2.36)	5.5 (2.41)
		95% CI	5.5, 14.8	0.7, 10.2
		Difference from placebo		
		LS Mean (SE)	4.7 (3.38)	
		95% CI	-1.9, 11.3	
		p-value	0.1647	
		Corrected Hedges' g (95% CI)	0.19 (-0.08, 0.46)	
Week 49	Change from Baseline	n (%)	92 (47.9%)	81 (44.0%)
		LS Mean (SE)	7.7 (2.46)	6.7 (2.60)
		95% CI	2.9, 12.6	1.6, 11.8
		Difference from placebo		
		LS Mean (SE)	1.0 (3.58)	
		95% CI	-6.0, 8.1	
		p-value	0.7714	
		Corrected Hedges' g (95% CI)	0.04 (-0.25, 0.34)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	90 (46.9%)	81 (44.0%)
		LS Mean (SE)	7.6 (2.50)	9.3 (2.62)
		95% CI	2.7, 12.5	4.2, 14.5
		Difference from placebo		
		LS Mean (SE)	-1.7 (3.63)	
		95% CI	-8.8, 5.4	
		p-value	0.6356	
		Corrected Hedges' g (95% CI)	-0.07 (-0.37, 0.23)	
Week 61	Change from Baseline	n (%)	79 (41.1%)	64 (34.8%)
		LS Mean (SE)	9.9 (2.60)	7.3 (2.81)
		95% CI	4.8, 15.0	1.7, 12.8
		Difference from placebo		
		LS Mean (SE)	2.7 (3.84)	
		95% CI	-4.9, 10.2	
		p-value	0.4903	
		Corrected Hedges' g (95% CI)	0.12 (-0.21, 0.45)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	80 (41.7%)	71 (38.6%)
		LS Mean (SE)	8.1 (2.60)	10.0 (2.74)
		95% CI	3.0, 13.2	4.6, 15.3
		Difference from placebo		
		LS Mean (SE)	-1.9 (3.78)	
		95% CI	-9.3, 5.6	
		p-value	0.6235	
		Corrected Hedges' g (95% CI)	-0.08 (-0.40, 0.24)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	61 (33.2%)
		LS Mean (SE)	8.4 (2.67)	11.2 (2.89)
		95% CI	3.2, 13.7	5.5, 16.9
		Difference from placebo		
		LS Mean (SE)	-2.8 (3.93)	
		95% CI	-10.5, 4.9	
		p-value	0.4812	
		Corrected Hedges' g (95% CI)	-0.12 (-0.46, 0.22)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	64 (33.3%)	56 (30.4%)
		LS Mean (SE)	6.3 (2.81)	10.4 (2.98)
		95% CI	0.8, 11.8	4.5, 16.2
		Difference from placebo		
		LS Mean (SE)	-4.1 (4.10)	
		95% CI	-12.2, 3.9	
		p-value	0.3167	
		Corrected Hedges' g (95% CI)	-0.18 (-0.54, 0.18)	
Week 85	Change from Baseline	n (%)	68 (35.4%)	58 (31.5%)
		LS Mean (SE)	7.2 (2.79)	10.1 (2.98)
		95% CI	1.8, 12.7	4.3, 16.0
		Difference from placebo		
		LS Mean (SE)	-2.9 (4.09)	
		95% CI	-10.9, 5.1	
		p-value	0.4788	
		Corrected Hedges' g (95% CI)	-0.13 (-0.48, 0.22)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	54 (28.1%)	48 (26.1%)
		LS Mean (SE)	13.2 (3.00)	7.4 (3.18)
		95% CI	7.3, 19.0	1.1, 13.6
		Difference from placebo		
		LS Mean (SE)	5.8 (4.39)	
		95% CI	-2.8, 14.4	
		p-value	0.1852	
		Corrected Hedges' g (95% CI)	0.26 (-0.13, 0.65)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	8.9 (2.86)	6.4 (3.13)
		95% CI	3.3, 14.6	0.3, 12.6
		Difference from placebo		
		LS Mean (SE)	2.5 (4.25)	
		95% CI	-5.8, 10.8	
		p-value	0.5551	
		Corrected Hedges' g (95% CI)	0.11 (-0.26, 0.48)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	54 (28.1%)	42 (22.8%)
		LS Mean (SE)	14.8 (3.03)	7.1 (3.35)
		95% CI	8.8, 20.7	0.5, 13.7
		Difference from placebo		
		LS Mean (SE)	7.7 (4.52)	
		95% CI	-1.2, 16.5	
		p-value	0.0900	
		Corrected Hedges' g (95% CI)	0.35 (-0.06, 0.75)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	13.7 (3.09)	6.8 (3.16)
		95% CI	7.6, 19.7	0.6, 13.0
		Difference from placebo		
		LS Mean (SE)	6.9 (4.43)	
		95% CI	-1.8, 15.5	
		p-value	0.1213	
		Corrected Hedges' g (95% CI)	0.30 (-0.09, 0.70)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	49 (25.5%)	41 (22.3%)
		LS Mean (SE)	12.0 (3.16)	7.5 (3.38)
		95% CI	5.8, 18.2	0.8, 14.1
		Difference from placebo		
		LS Mean (SE)	4.5 (4.64)	
		95% CI	-4.6, 13.6	
		p-value	0.3294	
		Corrected Hedges' g (95% CI)	0.20 (-0.21, 0.62)	
Week 121	Change from Baseline	n (%)	49 (25.5%)	50 (27.2%)
		LS Mean (SE)	8.1 (3.16)	9.7 (3.19)
		95% CI	1.9, 14.3	3.4, 16.0
		Difference from placebo		
		LS Mean (SE)	-1.6 (4.49)	
		95% CI	-10.4, 7.2	
		p-value	0.7183	
		Corrected Hedges' g (95% CI)	-0.07 (-0.47, 0.32)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	41 (22.3%)
		LS Mean (SE)	11.0 (3.33)	9.4 (3.40)
		95% CI	4.5, 17.6	2.7, 16.1
		Difference from placebo		
		LS Mean (SE)	1.6 (4.77)	
		95% CI	-7.7, 11.0	
		p-value	0.7331	
		Corrected Hedges' g (95% CI)	0.07 (-0.35, 0.50)	
Week 133	Change from Baseline	n (%)	46 (24.0%)	42 (22.8%)
		LS Mean (SE)	13.9 (3.26)	10.8 (3.41)
		95% CI	7.5, 20.3	4.1, 17.5
		Difference from placebo		
		LS Mean (SE)	3.1 (4.71)	
		95% CI	-6.1, 12.4	
		p-value	0.5078	
		Corrected Hedges' g (95% CI)	0.14 (-0.28, 0.56)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

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Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	45 (23.4%)	36 (19.6%)
		LS Mean (SE)	10.8 (3.32)	10.1 (3.62)
		95% CI	4.3, 17.4	3.0, 17.2
		Difference from placebo		
		LS Mean (SE)	0.8 (4.92)	
		95% CI	-8.9, 10.4	
		p-value	0.8760	
		Corrected Hedges' g (95% CI)	0.03 (-0.40, 0.47)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	30 (16.3%)
		LS Mean (SE)	11.9 (3.56)	6.5 (3.91)
		95% CI	4.9, 18.9	-1.1, 14.2
		Difference from placebo		
		LS Mean (SE)	5.4 (5.29)	
		95% CI	-5.0, 15.7	
		p-value	0.3111	
		Corrected Hedges' g (95% CI)	0.25 (-0.24, 0.73)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	35 (18.2%)	25 (13.6%)
		LS Mean (SE)	10.9 (3.72)	4.5 (4.25)
		95% CI	3.6, 18.2	-3.8, 12.8
		Difference from placebo		
		LS Mean (SE)	6.4 (5.66)	
		95% CI	-4.7, 17.5	
		p-value	0.2553	
		Corrected Hedges' g (95% CI)	0.29 (-0.22, 0.81)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	19 (10.3%)
		LS Mean (SE)	1.6 (4.14)	3.5 (4.93)
		95% CI	-6.5, 9.7	-6.2, 13.1
		Difference from placebo		
		LS Mean (SE)	-1.9 (6.40)	
		95% CI	-14.4, 10.7	
		p-value	0.7709	
		Corrected Hedges' g (95% CI)	-0.09 (-0.68, 0.51)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	20 (10.4%)	17 (9.2%)
		LS Mean (SE)	15.6 (4.66)	6.1 (5.26)
		95% CI	6.4, 24.7	-4.2, 16.4
		Difference from placebo		
		LS Mean (SE)	9.5 (6.98)	
		95% CI	-4.2, 23.2	
		p-value	0.1736	
		Corrected Hedges' g (95% CI)	0.44 (-0.22, 1.09)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	10 (5.4%)
		LS Mean (SE)	5.8 (5.10)	15.7 (6.39)
		95% CI	-4.2, 15.8	3.2, 28.3
		Difference from placebo		
		LS Mean (SE)	-9.9 (8.22)	
		95% CI	-26.0, 6.2	
		p-value	0.2284	
		Corrected Hedges' g (95% CI)	-0.46 (-1.25, 0.33)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.1802 Summary of Analysis of EORTC-QLQ-EN24 Dimension Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	9.5 (6.38)	4.9 (7.32)
		95% CI	-3.0, 22.0	-9.5, 19.2
		Difference from placebo		
		LS Mean (SE)	4.6 (8.88)	
		95% CI	-12.8, 22.0	
		p-value	0.6027	
		Corrected Hedges' g (95% CI)	0.19 (-0.63, 1.01)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	7 (3.8%)
		LS Mean (SE)	43.4 (7.84)	4.8 (7.82)
		95% CI	28.0, 58.8	-10.6, 20.1
		Difference from placebo		
		LS Mean (SE)	38.6 (11.20)	
		95% CI	16.7, 60.6	
		p-value	0.0006	
		Corrected Hedges' g (95% CI)	1.63 (0.50, 2.77)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_1802_en24_mmrm.sas, Output: t_2_1802_en24_mmrm.rtf, Generated on: 07AUG2024 15:29, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Overall	Change from Baseline	n (%)	180 (93.8%)	174 (94.6%)
		LS Mean (SE)	-1.6 (0.94)	1.6 (1.01)
		95% CI	-3.5, 0.2	-0.4, 3.6
		Difference from placebo		
		LS Mean (SE)	-3.2 (1.38)	
		95% CI	-5.9, -0.5	
		p-value	0.0217	
		Corrected Hedges' g (95% CI)	-0.25 (-0.45, -0.04)	
Week 4	Change from Baseline	n (%)	175 (91.1%)	171 (92.9%)
		LS Mean (SE)	-0.7 (1.23)	1.7 (1.25)
		95% CI	-3.1, 1.8	-0.8, 4.1
		Difference from placebo		
		LS Mean (SE)	-2.3 (1.75)	
		95% CI	-5.8, 1.1	
		p-value	0.1806	
		Corrected Hedges' g (95% CI)	-0.14 (-0.35, 0.07)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 7	Change from Baseline	n (%)	168 (87.5%)	163 (88.6%)
		LS Mean (SE)	-0.0 (1.14)	2.2 (1.16)
		95% CI	-2.2, 2.2	-0.1, 4.4
		Difference from placebo		
		LS Mean (SE)	-2.2 (1.62)	
		95% CI	-5.3, 1.0	
		p-value	0.1851	
		Corrected Hedges' g (95% CI)	-0.15 (-0.36, 0.07)	
Week 10	Change from Baseline	n (%)	165 (85.9%)	155 (84.2%)
		LS Mean (SE)	-1.6 (1.15)	1.2 (1.18)
		95% CI	-3.9, 0.6	-1.1, 3.5
		Difference from placebo		
		LS Mean (SE)	-2.8 (1.64)	
		95% CI	-6.0, 0.4	
		p-value	0.0884	
		Corrected Hedges' g (95% CI)	-0.19 (-0.41, 0.03)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 13	Change from Baseline	n (%)	155 (80.7%)	148 (80.4%)
		LS Mean (SE)	-1.1 (1.22)	0.3 (1.25)
		95% CI	-3.5, 1.3	-2.2, 2.7
		Difference from placebo		
		LS Mean (SE)	-1.4 (1.75)	
		95% CI	-4.8, 2.1	
		p-value	0.4301	
		Corrected Hedges' g (95% CI)	-0.09 (-0.32, 0.13)	
Week 16	Change from Baseline	n (%)	151 (78.6%)	148 (80.4%)
		LS Mean (SE)	-1.9 (1.22)	0.3 (1.24)
		95% CI	-4.3, 0.5	-2.1, 2.7
		Difference from placebo		
		LS Mean (SE)	-2.2 (1.73)	
		95% CI	-5.6, 1.2	
		p-value	0.2023	
		Corrected Hedges' g (95% CI)	-0.15 (-0.37, 0.08)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 19	Change from Baseline	n (%)	153 (79.7%)	148 (80.4%)
		LS Mean (SE)	-3.1 (1.19)	0.8 (1.22)
		95% CI	-5.5, -0.8	-1.6, 3.2
		Difference from placebo		
		LS Mean (SE)	-4.0 (1.70)	
		95% CI	-7.3, -0.6	
		p-value	0.0198	
		Corrected Hedges' g (95% CI)	-0.27 (-0.50, -0.04)	
Week 25	Change from Baseline	n (%)	136 (70.8%)	131 (71.2%)
		LS Mean (SE)	-1.0 (1.27)	1.6 (1.29)
		95% CI	-3.5, 1.5	-1.0, 4.1
		Difference from placebo		
		LS Mean (SE)	-2.6 (1.81)	
		95% CI	-6.1, 1.0	
		p-value	0.1559	
		Corrected Hedges' g (95% CI)	-0.17 (-0.41, 0.07)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 31	Change from Baseline	n (%)	126 (65.6%)	130 (70.7%)
		LS Mean (SE)	-0.6 (1.22)	3.5 (1.22)
		95% CI	-3.0, 1.8	1.1, 5.9
		Difference from placebo		
		LS Mean (SE)	-4.1 (1.72)	
		95% CI	-7.5, -0.8	
		p-value	0.0167	
		Corrected Hedges' g (95% CI)	-0.30 (-0.55, -0.05)	
Week 37	Change from Baseline	n (%)	114 (59.4%)	106 (57.6%)
		LS Mean (SE)	0.3 (1.29)	0.5 (1.32)
		95% CI	-2.2, 2.9	-2.1, 3.1
		Difference from placebo		
		LS Mean (SE)	-0.2 (1.84)	
		95% CI	-3.8, 3.4	
		p-value	0.9141	
		Corrected Hedges' g (95% CI)	-0.01 (-0.28, 0.25)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 43	Change from Baseline	n (%)	106 (55.2%)	105 (57.1%)
		LS Mean (SE)	0.5 (1.21)	3.5 (1.23)
		95% CI	-1.8, 2.9	1.1, 5.9
		Difference from placebo		
		LS Mean (SE)	-2.9 (1.72)	
		95% CI	-6.3, 0.4	
		p-value	0.0888	
		Corrected Hedges' g (95% CI)	-0.23 (-0.50, 0.04)	
Week 49	Change from Baseline	n (%)	90 (46.9%)	82 (44.6%)
		LS Mean (SE)	-0.2 (1.38)	1.2 (1.43)
		95% CI	-2.9, 2.5	-1.6, 4.0
		Difference from placebo		
		LS Mean (SE)	-1.4 (1.98)	
		95% CI	-5.3, 2.5	
		p-value	0.4887	
		Corrected Hedges' g (95% CI)	-0.11 (-0.40, 0.19)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 55	Change from Baseline	n (%)	91 (47.4%)	82 (44.6%)
		LS Mean (SE)	-1.6 (1.52)	0.4 (1.58)
		95% CI	-4.6, 1.4	-2.7, 3.5
		Difference from placebo		
		LS Mean (SE)	-2.0 (2.19)	
		95% CI	-6.3, 2.3	
		p-value	0.3642	
		Corrected Hedges' g (95% CI)	-0.14 (-0.44, 0.16)	
Week 61	Change from Baseline	n (%)	77 (40.1%)	66 (35.9%)
		LS Mean (SE)	-0.7 (1.56)	1.5 (1.64)
		95% CI	-3.8, 2.3	-1.7, 4.8
		Difference from placebo		
		LS Mean (SE)	-2.3 (2.27)	
		95% CI	-6.7, 2.2	
		p-value	0.3180	
		Corrected Hedges' g (95% CI)	-0.17 (-0.50, 0.16)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 67	Change from Baseline	n (%)	81 (42.2%)	72 (39.1%)
		LS Mean (SE)	-0.2 (1.34)	1.3 (1.40)
		95% CI	-2.8, 2.4	-1.5, 4.0
		Difference from placebo		
		LS Mean (SE)	-1.5 (1.93)	
		95% CI	-5.3, 2.3	
		p-value	0.4453	
		Corrected Hedges' g (95% CI)	-0.12 (-0.44, 0.19)	
Week 73	Change from Baseline	n (%)	74 (38.5%)	62 (33.7%)
		LS Mean (SE)	-0.3 (1.47)	0.2 (1.57)
		95% CI	-3.2, 2.6	-2.9, 3.3
		Difference from placebo		
		LS Mean (SE)	-0.5 (2.15)	
		95% CI	-4.7, 3.7	
		p-value	0.8194	
		Corrected Hedges' g (95% CI)	-0.04 (-0.38, 0.30)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 79	Change from Baseline	n (%)	64 (33.3%)	57 (31.0%)
		LS Mean (SE)	-1.2 (1.45)	0.3 (1.52)
		95% CI	-4.0, 1.7	-2.7, 3.3
		Difference from placebo		
		LS Mean (SE)	-1.4 (2.10)	
		95% CI	-5.6, 2.7	
		p-value	0.4965	
		Corrected Hedges' g (95% CI)	-0.12 (-0.48, 0.23)	
Week 85	Change from Baseline	n (%)	67 (34.9%)	58 (31.5%)
		LS Mean (SE)	-1.8 (1.38)	1.4 (1.46)
		95% CI	-4.6, 0.9	-1.4, 4.3
		Difference from placebo		
		LS Mean (SE)	-3.3 (2.01)	
		95% CI	-7.2, 0.7	
		p-value	0.1059	
		Corrected Hedges' g (95% CI)	-0.29 (-0.64, 0.06)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 91	Change from Baseline	n (%)	54 (28.1%)	49 (26.6%)
		LS Mean (SE)	-1.7 (1.72)	1.7 (1.81)
		95% CI	-5.1, 1.7	-1.9, 5.3
		Difference from placebo		
		LS Mean (SE)	-3.4 (2.49)	
		95% CI	-8.3, 1.6	
		p-value	0.1785	
		Corrected Hedges' g (95% CI)	-0.26 (-0.65, 0.12)	
Week 97	Change from Baseline	n (%)	63 (32.8%)	52 (28.3%)
		LS Mean (SE)	-0.6 (1.40)	0.9 (1.51)
		95% CI	-3.4, 2.2	-2.0, 3.9
		Difference from placebo		
		LS Mean (SE)	-1.5 (2.06)	
		95% CI	-5.6, 2.5	
		p-value	0.4592	
		Corrected Hedges' g (95% CI)	-0.14 (-0.51, 0.23)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 103	Change from Baseline	n (%)	53 (27.6%)	43 (23.4%)
		LS Mean (SE)	-1.0 (1.51)	2.0 (1.63)
		95% CI	-4.0, 1.9	-1.2, 5.2
		Difference from placebo		
		LS Mean (SE)	-3.0 (2.21)	
		95% CI	-7.4, 1.3	
		p-value	0.1702	
		Corrected Hedges' g (95% CI)	-0.28 (-0.68, 0.12)	
Week 109	Change from Baseline	n (%)	51 (26.6%)	51 (27.7%)
		LS Mean (SE)	-0.9 (1.49)	2.5 (1.52)
		95% CI	-3.8, 2.0	-0.5, 5.5
		Difference from placebo		
		LS Mean (SE)	-3.4 (2.13)	
		95% CI	-7.6, 0.8	
		p-value	0.1092	
		Corrected Hedges' g (95% CI)	-0.32 (-0.71, 0.07)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 115	Change from Baseline	n (%)	48 (25.0%)	42 (22.8%)
		LS Mean (SE)	0.8 (1.41)	2.0 (1.48)
		95% CI	-2.0, 3.6	-0.9, 4.9
		Difference from placebo		
		LS Mean (SE)	-1.2 (2.05)	
		95% CI	-5.2, 2.9	
		p-value	0.5646	
		Corrected Hedges' g (95% CI)	-0.12 (-0.54, 0.29)	
Week 121	Change from Baseline	n (%)	50 (26.0%)	50 (27.2%)
		LS Mean (SE)	-0.4 (1.70)	-1.1 (1.72)
		95% CI	-3.7, 3.0	-4.5, 2.3
		Difference from placebo		
		LS Mean (SE)	0.7 (2.41)	
		95% CI	-4.1, 5.5	
		p-value	0.7738	
		Corrected Hedges' g (95% CI)	0.06 (-0.34, 0.45)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 127	Change from Baseline	n (%)	44 (22.9%)	43 (23.4%)
		LS Mean (SE)	-0.5 (1.43)	1.6 (1.46)
		95% CI	-3.3, 2.4	-1.2, 4.5
		Difference from placebo		
		LS Mean (SE)	-2.1 (2.04)	
		95% CI	-6.1, 1.9	
		p-value	0.3016	
		Corrected Hedges' g (95% CI)	-0.22 (-0.64, 0.20)	
Week 133	Change from Baseline	n (%)	45 (23.4%)	43 (23.4%)
		LS Mean (SE)	0.4 (1.44)	1.1 (1.48)
		95% CI	-2.4, 3.3	-1.8, 4.0
		Difference from placebo		
		LS Mean (SE)	-0.6 (2.07)	
		95% CI	-4.7, 3.4	
		p-value	0.7590	
		Corrected Hedges' g (95% CI)	-0.06 (-0.48, 0.35)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 139	Change from Baseline	n (%)	44 (22.9%)	36 (19.6%)
		LS Mean (SE)	-0.2 (1.48)	0.8 (1.59)
		95% CI	-3.1, 2.7	-2.4, 3.9
		Difference from placebo		
		LS Mean (SE)	-1.0 (2.17)	
		95% CI	-5.3, 3.3	
		p-value	0.6556	
		Corrected Hedges' g (95% CI)	-0.10 (-0.54, 0.34)	
Week 145	Change from Baseline	n (%)	37 (19.3%)	31 (16.8%)
		LS Mean (SE)	0.8 (1.25)	3.5 (1.34)
		95% CI	-1.7, 3.3	0.9, 6.2
		Difference from placebo		
		LS Mean (SE)	-2.7 (1.83)	
		95% CI	-6.3, 0.9	
		p-value	0.1368	
		Corrected Hedges' g (95% CI)	-0.36 (-0.84, 0.12)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 151	Change from Baseline	n (%)	34 (17.7%)	24 (13.0%)
		LS Mean (SE)	-1.1 (1.64)	3.0 (1.87)
		95% CI	-4.3, 2.2	-0.7, 6.7
		Difference from placebo		
		LS Mean (SE)	-4.0 (2.48)	
		95% CI	-9.0, 0.9	
		p-value	0.1076	
		Corrected Hedges' g (95% CI)	-0.42 (-0.95, 0.11)	
Week 157	Change from Baseline	n (%)	26 (13.5%)	21 (11.4%)
		LS Mean (SE)	-3.9 (1.81)	1.7 (1.98)
		95% CI	-7.5, -0.3	-2.3, 5.6
		Difference from placebo		
		LS Mean (SE)	-5.6 (2.69)	
		95% CI	-11.0, -0.2	
		p-value	0.0408	
		Corrected Hedges' g (95% CI)	-0.60 (-1.19, -0.01)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 163	Change from Baseline	n (%)	21 (10.9%)	18 (9.8%)
		LS Mean (SE)	-4.4 (2.44)	1.1 (2.66)
		95% CI	-9.3, 0.5	-4.3, 6.4
		Difference from placebo		
		LS Mean (SE)	-5.4 (3.60)	
		95% CI	-12.7, 1.8	
		p-value	0.1379	
		Corrected Hedges' g (95% CI)	-0.47 (-1.11, 0.16)	
Week 169	Change from Baseline	n (%)	17 (8.9%)	10 (5.4%)
		LS Mean (SE)	-0.1 (2.10)	2.9 (2.56)
		95% CI	-4.4, 4.2	-2.4, 8.1
		Difference from placebo		
		LS Mean (SE)	-2.9 (3.29)	
		95% CI	-9.7, 3.8	
		p-value	0.3781	
		Corrected Hedges' g (95% CI)	-0.34 (-1.12, 0.45)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 175	Change from Baseline	n (%)	12 (6.3%)	11 (6.0%)
		LS Mean (SE)	-10.3 (3.34)	0.8 (3.45)
		95% CI	-17.2, -3.4	-6.3, 7.9
		Difference from placebo		
		LS Mean (SE)	-11.1 (4.74)	
		95% CI	-20.9, -1.3	
		p-value	0.0281	
		Corrected Hedges' g (95% CI)	-0.93 (-1.79, -0.07)	
Week 181	Change from Baseline	n (%)	9 (4.7%)	8 (4.3%)
		LS Mean (SE)	-6.4 (4.10)	3.0 (4.29)
		95% CI	-15.1, 2.2	-6.1, 12.1
		Difference from placebo		
		LS Mean (SE)	-9.4 (5.90)	
		95% CI	-21.9, 3.1	
		p-value	0.1312	
		Corrected Hedges' g (95% CI)	-0.73 (-1.71, 0.25)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.
Note: Corrected Hedges' g (95% CI) are derived from the LS Means and associated SEs.
Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.
Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Table 2.2502 Summary of Analysis of EQ-5D-5L Visual Analogue Scores Change from Baseline over Time – Mixed-effects Model for Repeated Measures (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ5D02-EQ VAS Score

Analysis Timepoint	Variable	Statistic	Dostarlimab + Paclitaxel/Carboplatin (N=192)	Placebo + Paclitaxel/Carboplatin (N=184)
Week 187	Change from Baseline	n (%)	5 (2.6%)	2 (1.1%)
		LS Mean (SE)	-11.0 (6.86)	3.9 (10.91)
		95% CI	-29.3, 7.4	-25.7, 33.4
		Difference from placebo		
		LS Mean (SE)	-14.9 (13.46)	
		95% CI	-51.2, 21.5	
		p-value	0.3273	
		Corrected Hedges' g (95% CI)	-0.81 (-2.51, 0.88)	

LS = Least squares; SE = Standard error, Only patients who have a baseline assessment are included.

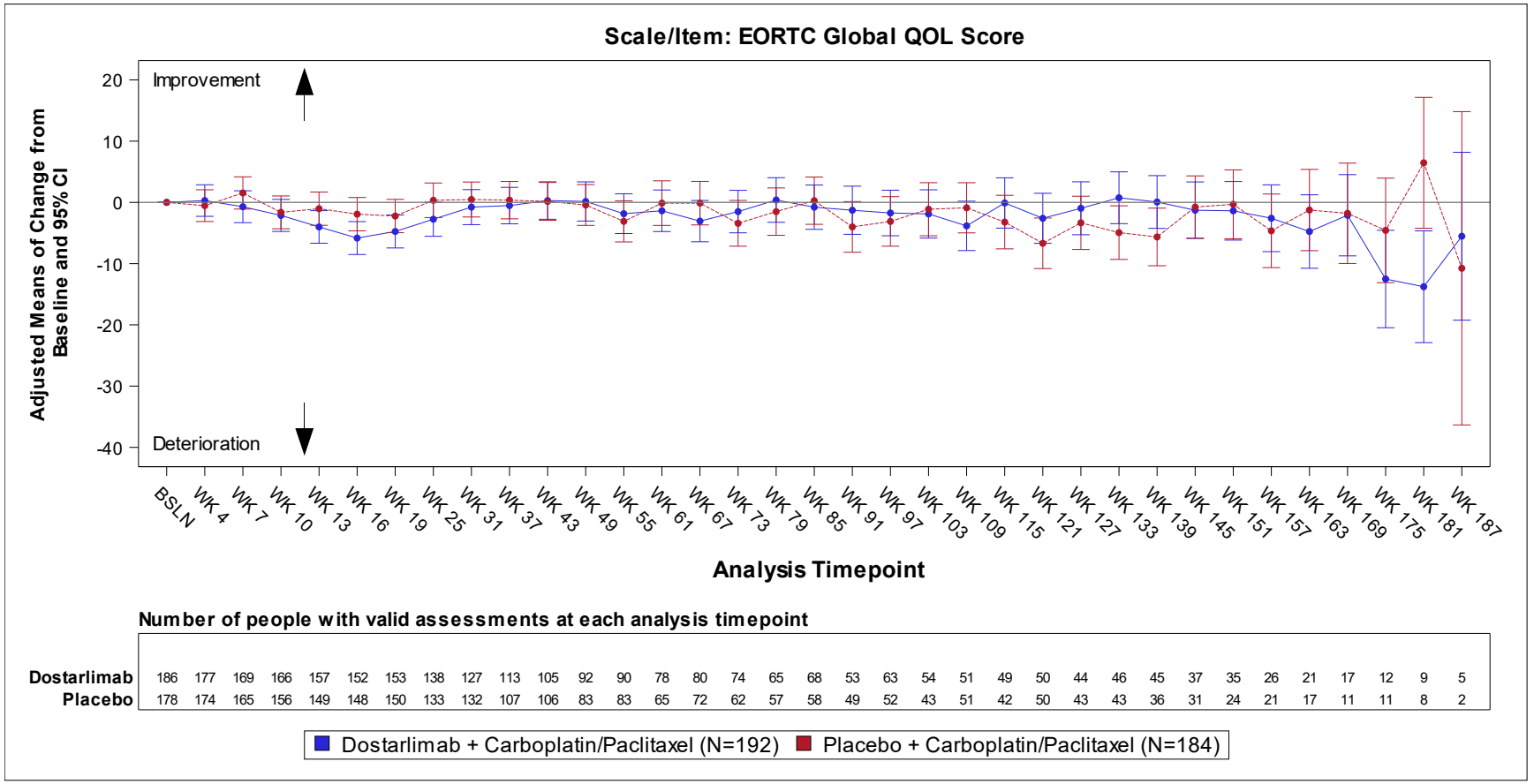
Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An ARH(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Corrected Hedges’ g (95% CI) are derived from the LS Means and associated SEs.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis.

Program: t_2_2502_eq5d_mmrm.sas, Output: t_2_2502_eq5d_mmrm.rtf, Generated on: 07AUG2024 13:35, Data Cutoff Date: 22SEP2023

Figure 2.0802 EORTC-QLQ-C30 Domain Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



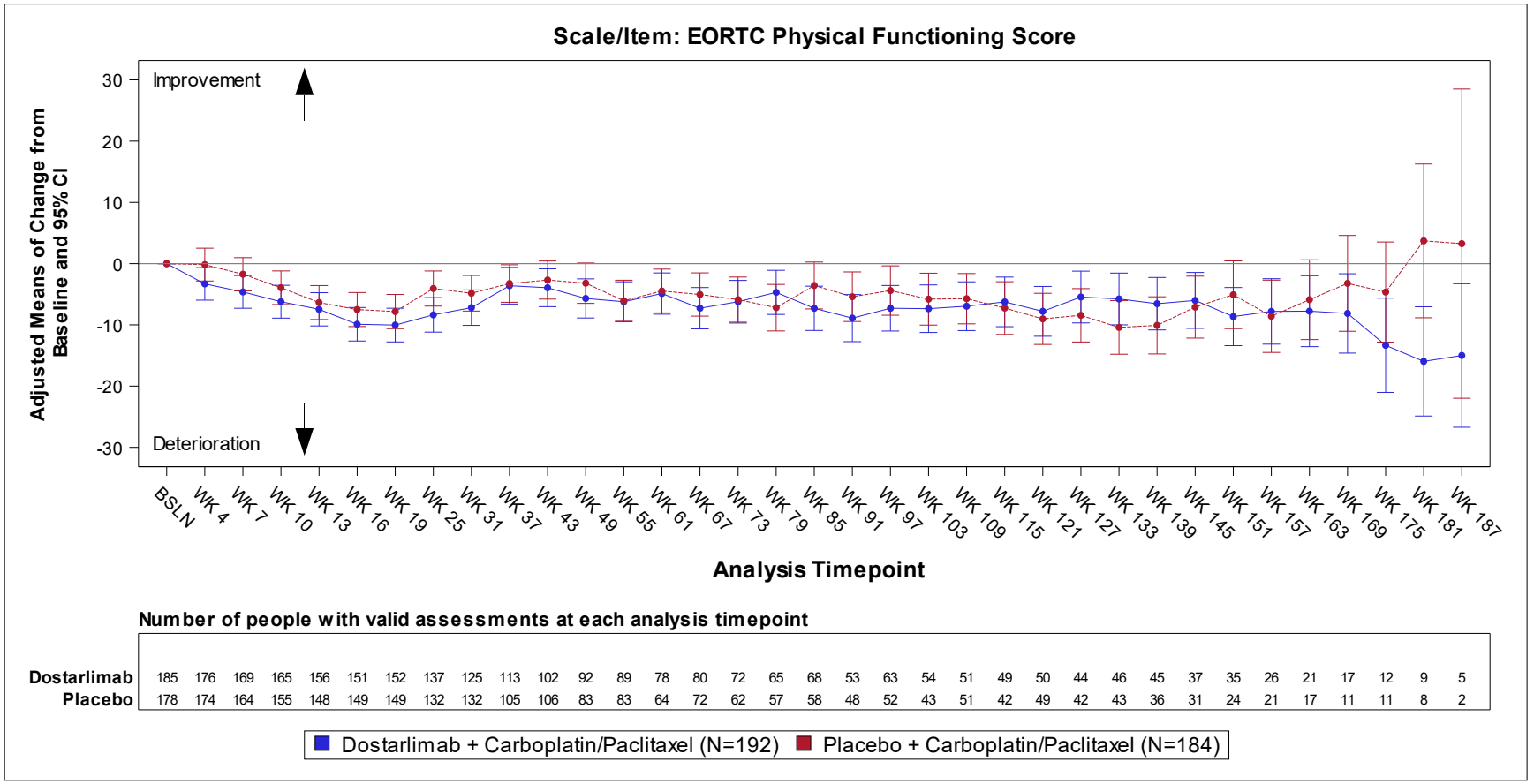
CI = Confidence Intervals, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis

Program: f_2_0802_q30_mmrm.sas, Output: f_2_0802_q30_mmrm.rtf, Generated on: 14AUG2024 12:05, Data Cutoff Date: 22SEP2023

Figure 2.0802 EORTC-QLQ-C30 Domain Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



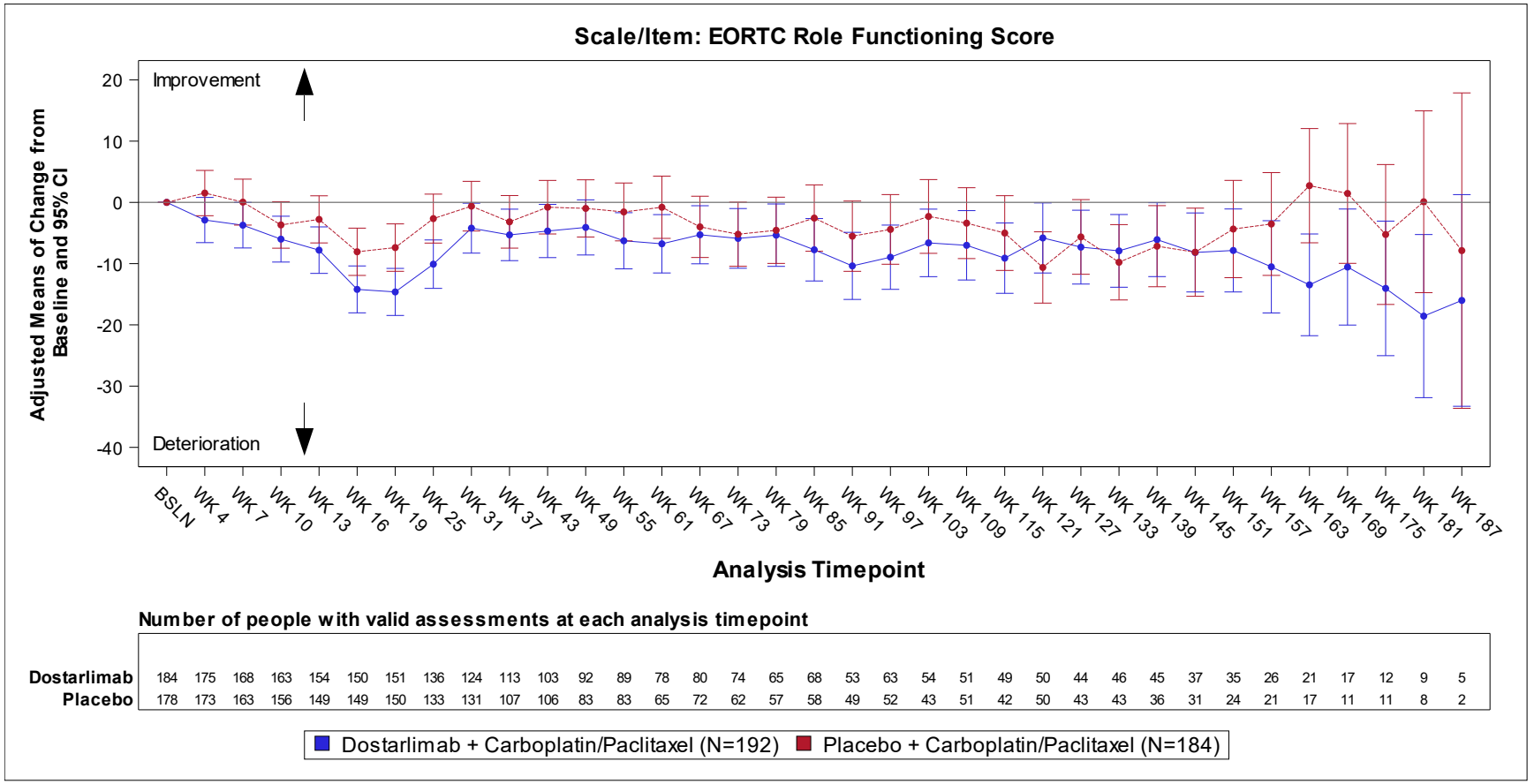
CI = Confidence Intervals, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis

Program: f_2_0802_q30_mmrm.sas, Output: f_2_0802_q30_mmrm.rtf, Generated on: 14AUG2024 12:05, Data Cutoff Date: 22SEP2023

Figure 2.0802 EORTC-QLQ-C30 Domain Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



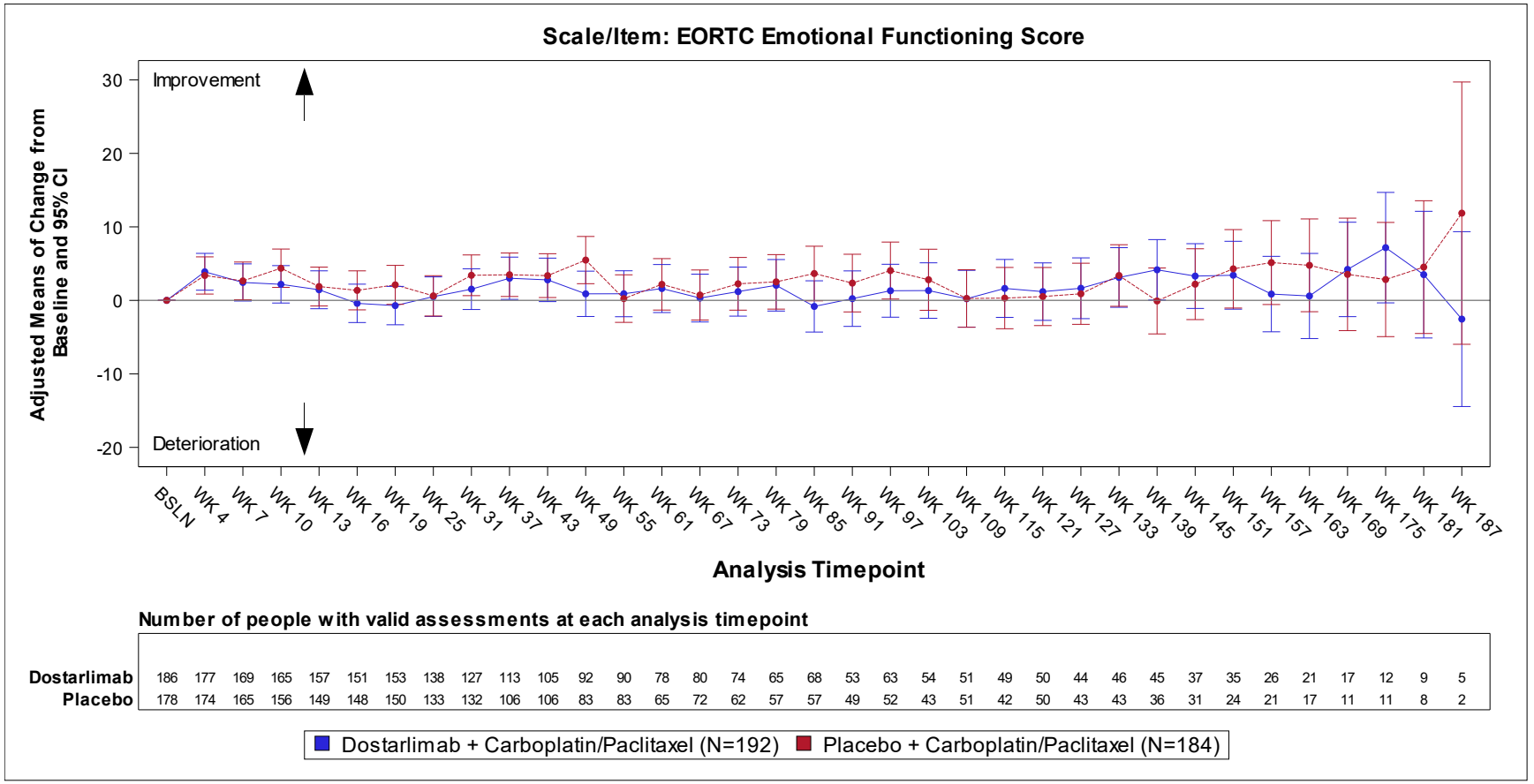
CI = Confidence Intervals, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis

Program: f_2_0802_q30_mmrm.sas, Output: f_2_0802_q30_mmrm.rtf, Generated on: 14AUG2024 12:05, Data Cutoff Date: 22SEP2023

Figure 2.0802 EORTC-QLQ-C30 Domain Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



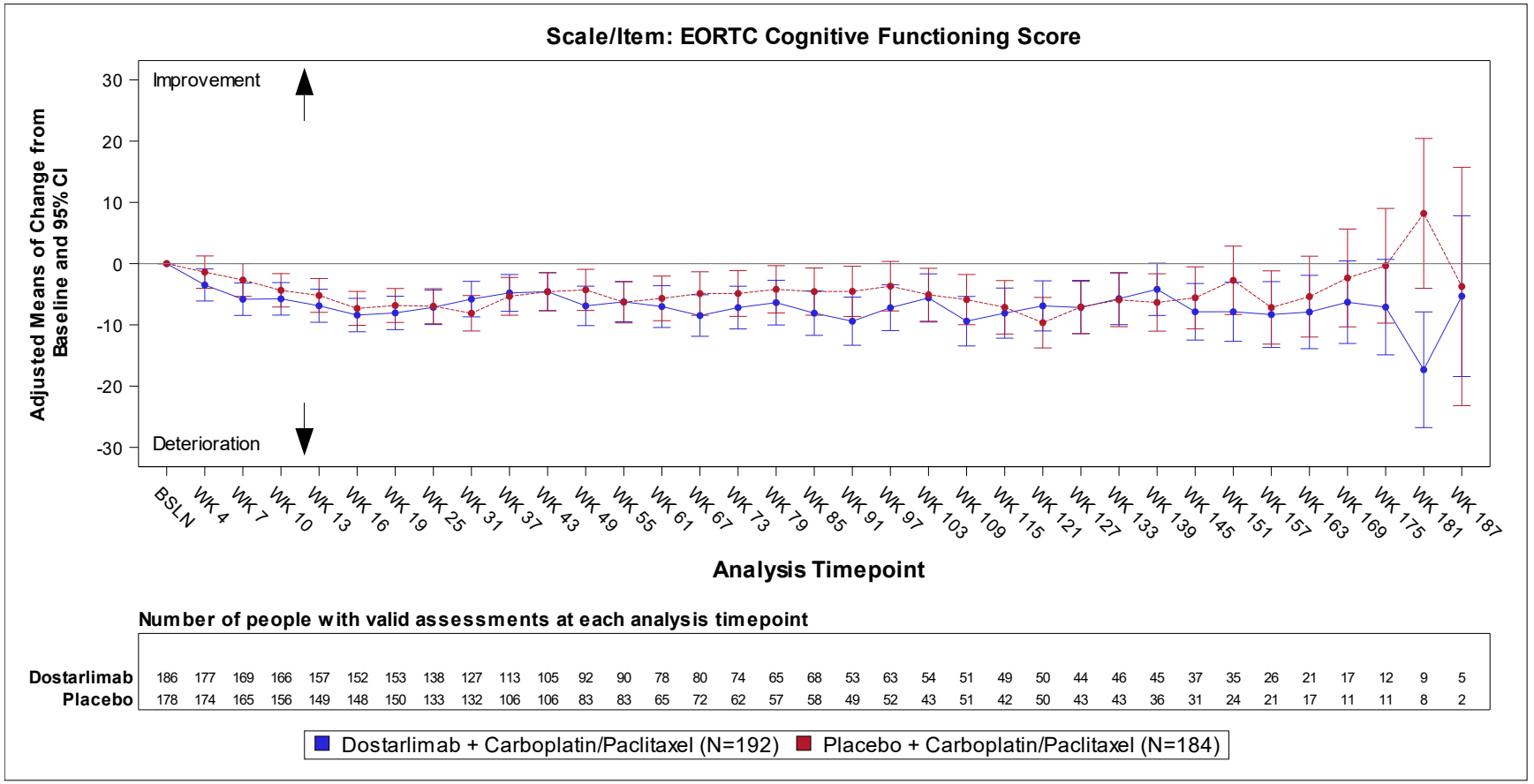
CI = Confidence Intervals, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis

Program: f_2_0802_q30_mmrm.sas, Output: f_2_0802_q30_mmrm.rtf, Generated on: 14AUG2024 12:05, Data Cutoff Date: 22SEP2023

Figure 2.0802 EORTC-QLQ-C30 Domain Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



CI = Confidence Intervals, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis

Program: f_2_0802_q30_mmrm.sas, Output: f_2_0802_q30_mmrm.rtf, Generated on: 14AUG2024 12:05, Data Cutoff Date: 22SEP2023

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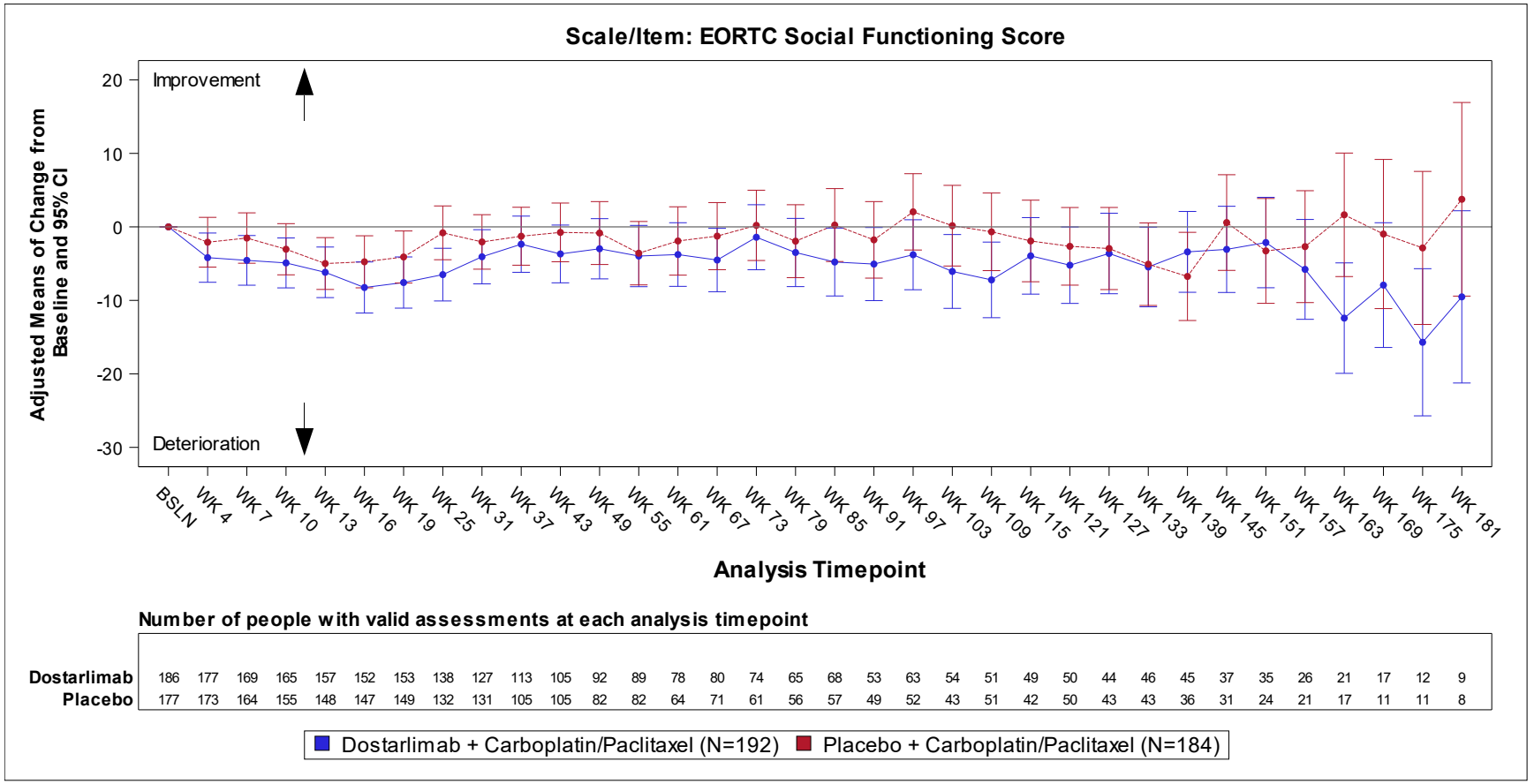

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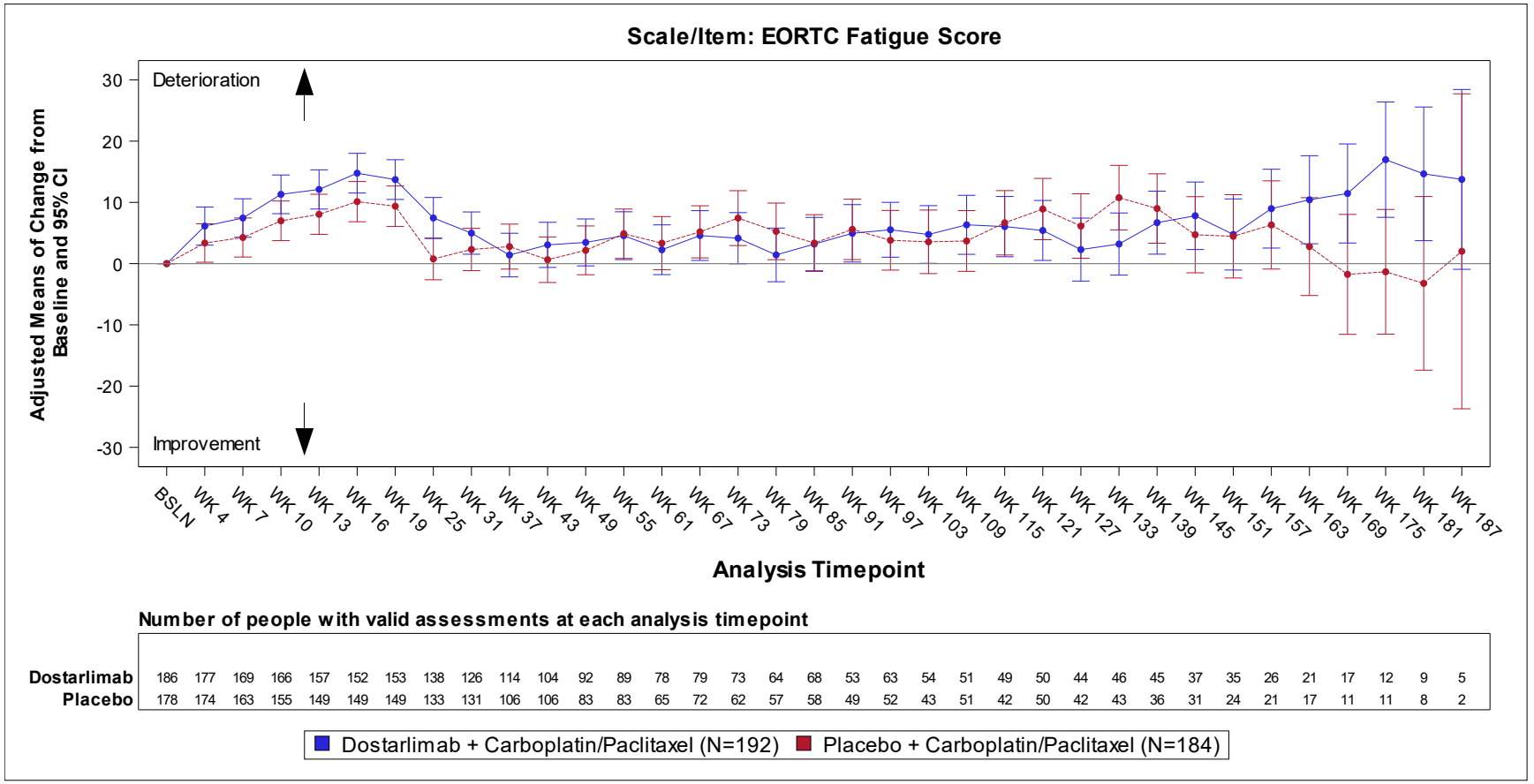

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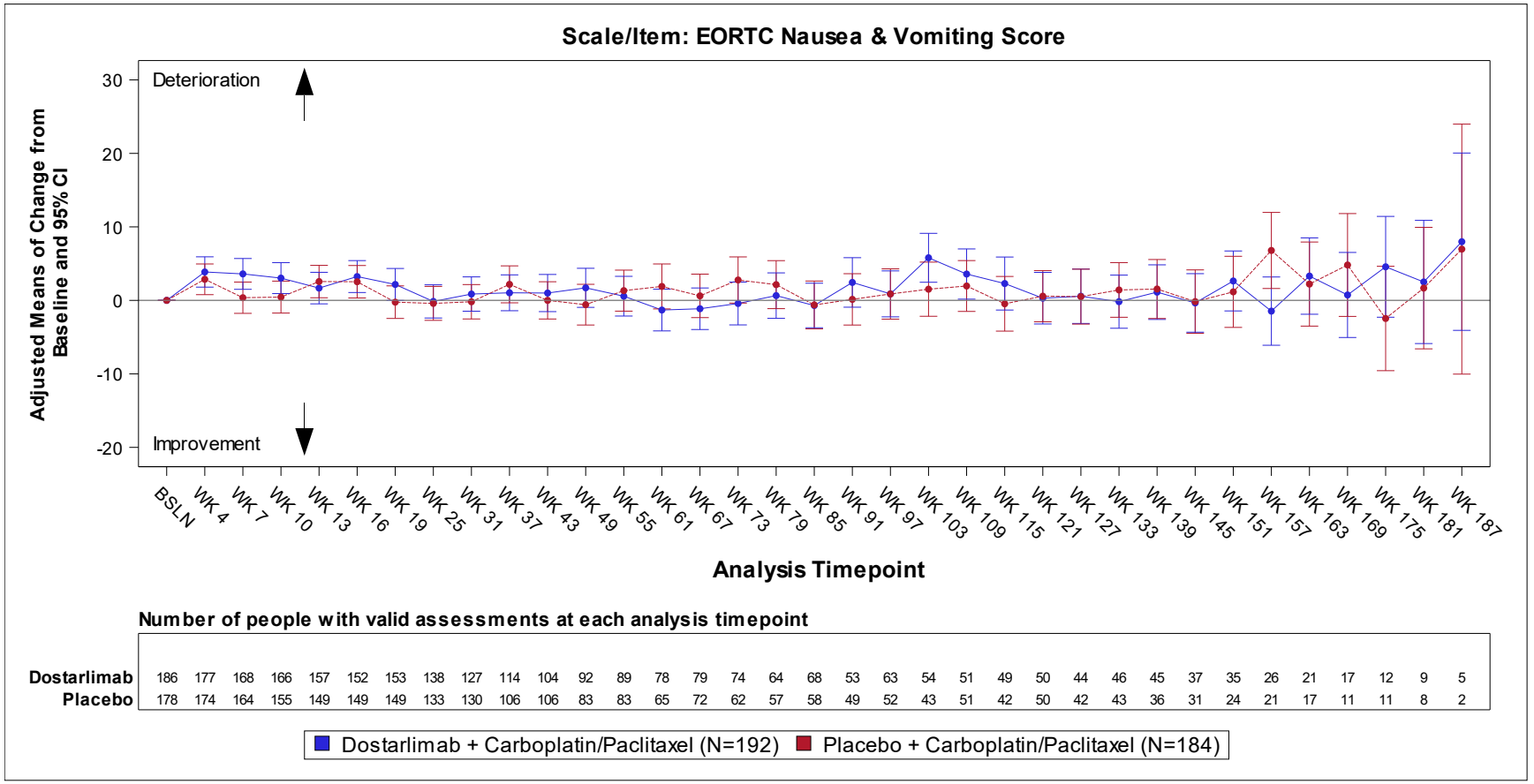

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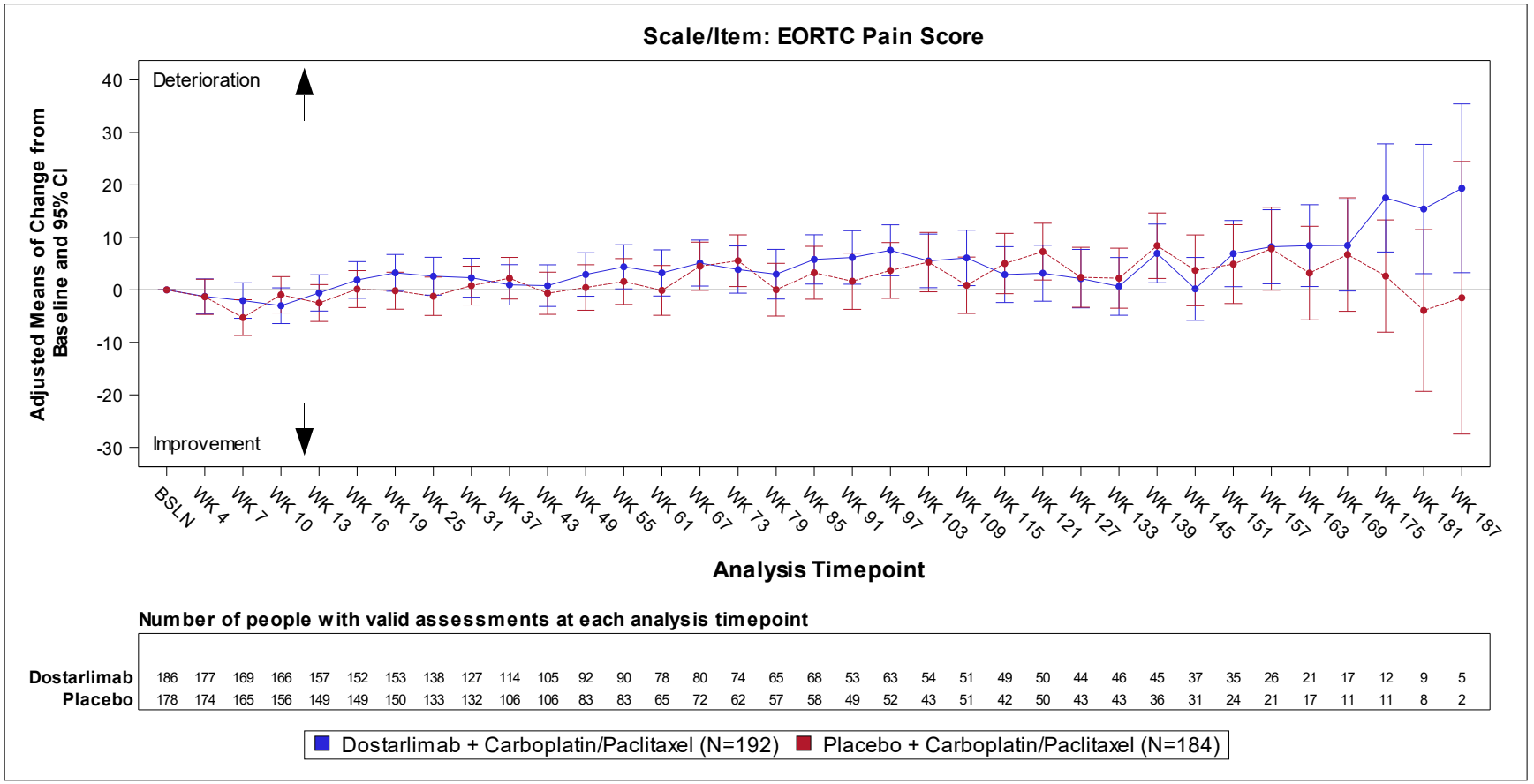

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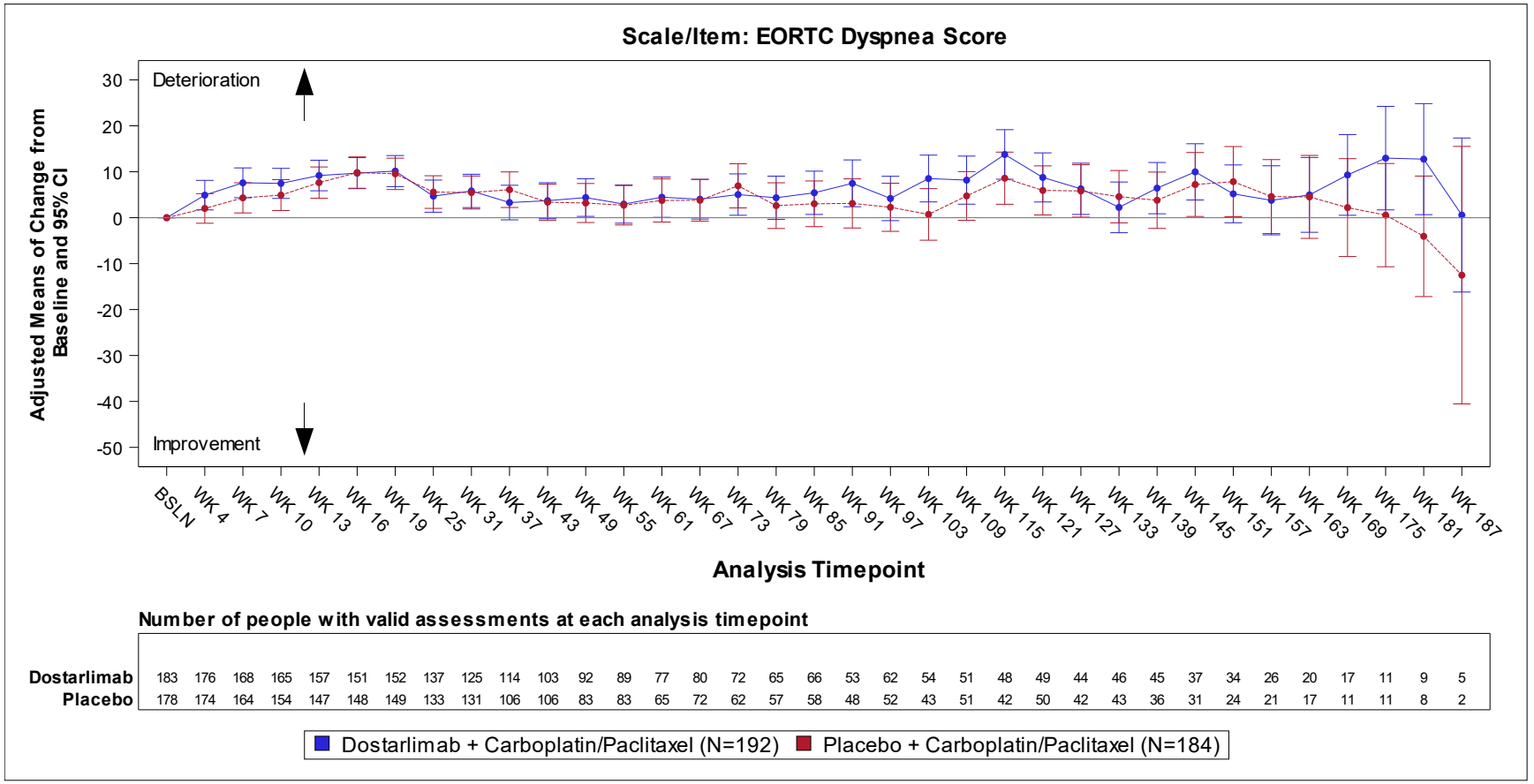

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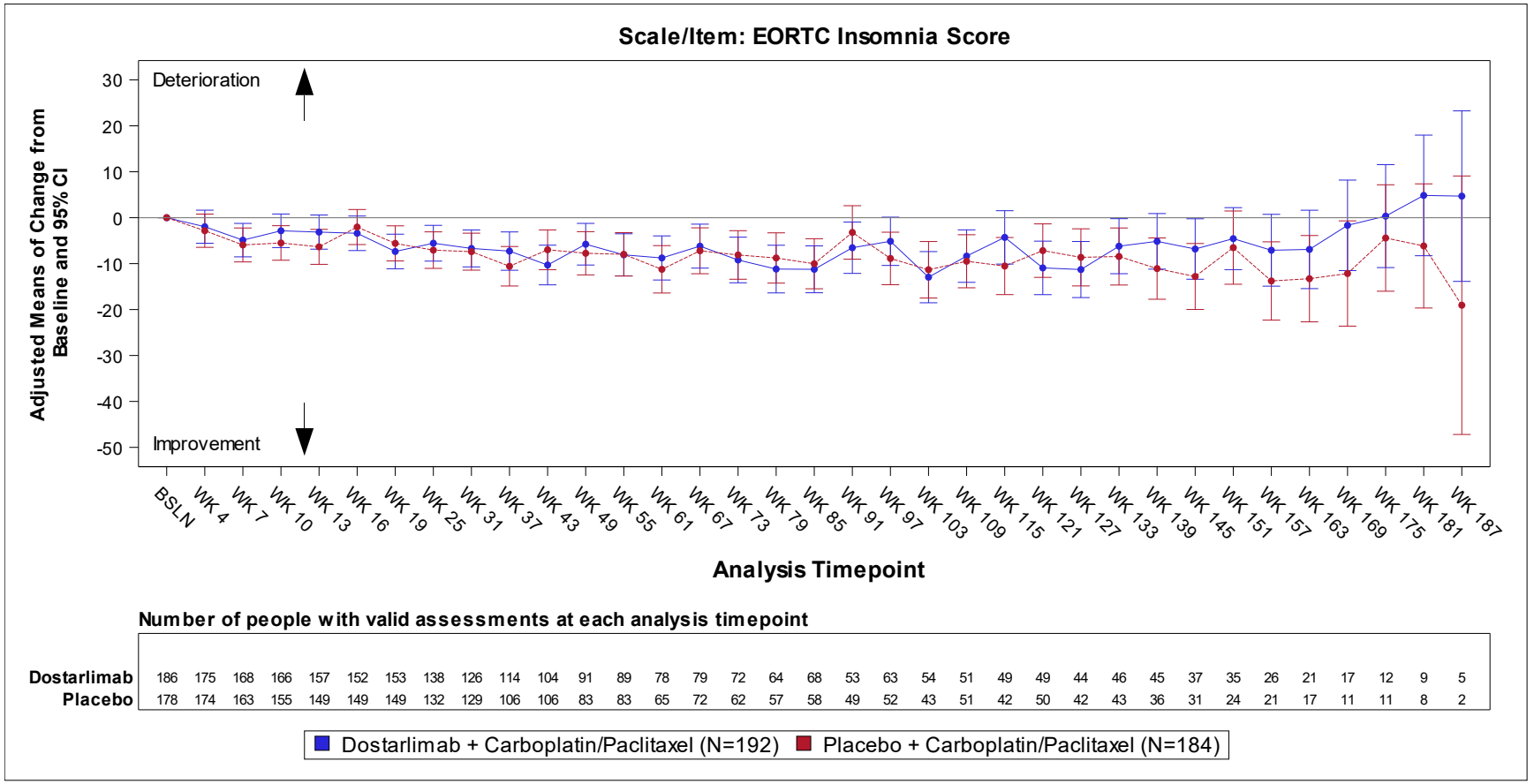

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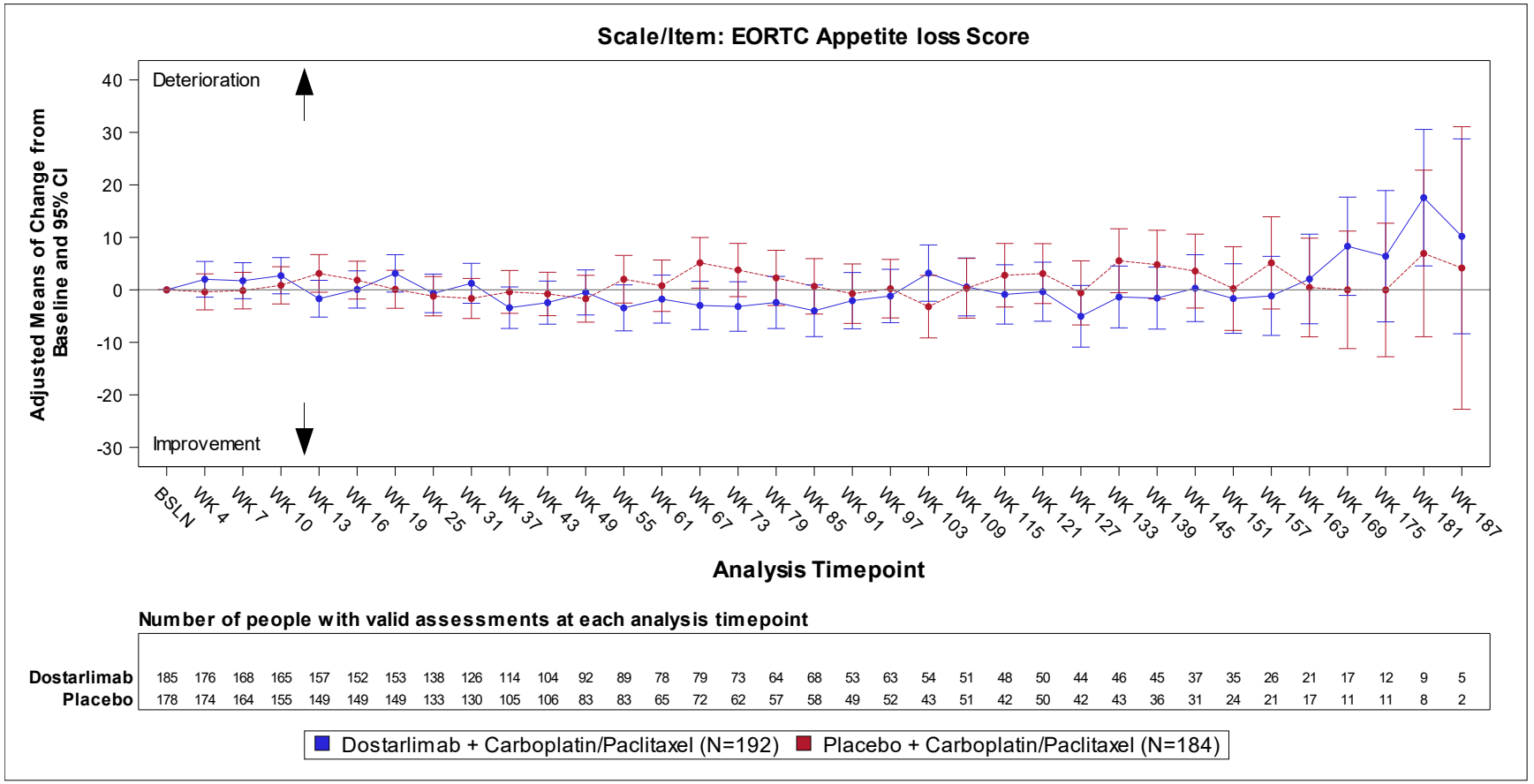

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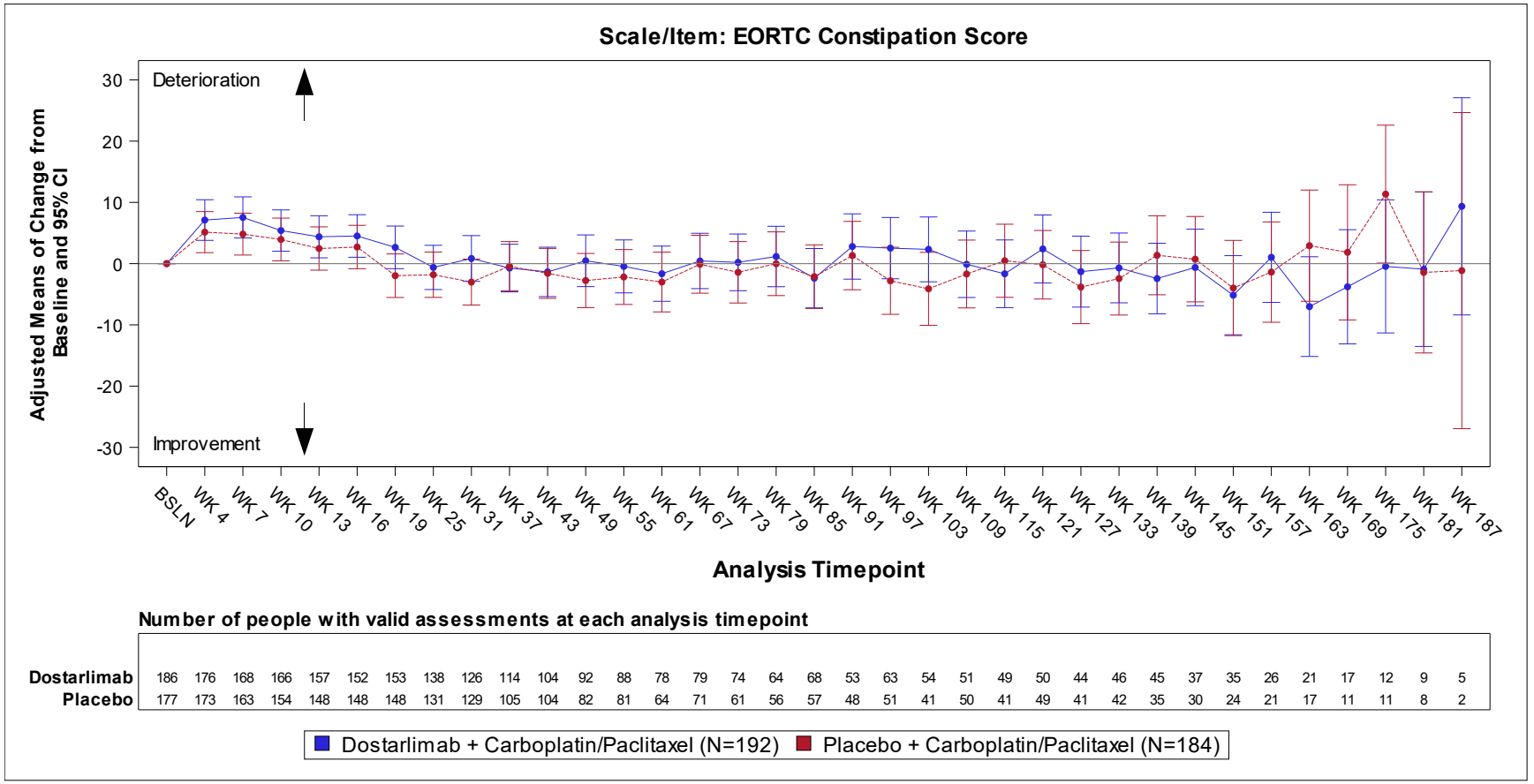
Figure 2.0802 EORTC-QLQ-C30 Domain Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



CI = Confidence Intervals, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

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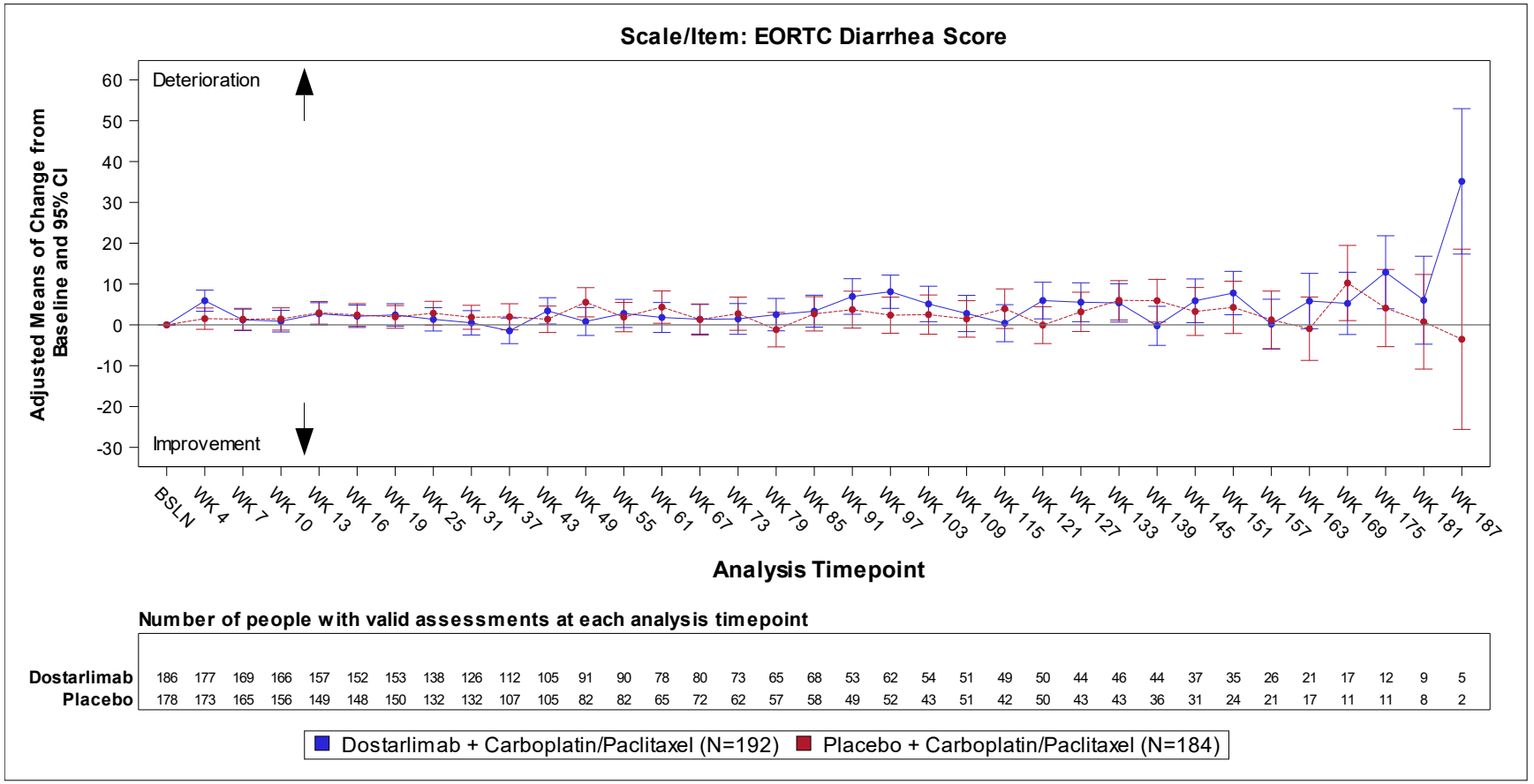

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Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis

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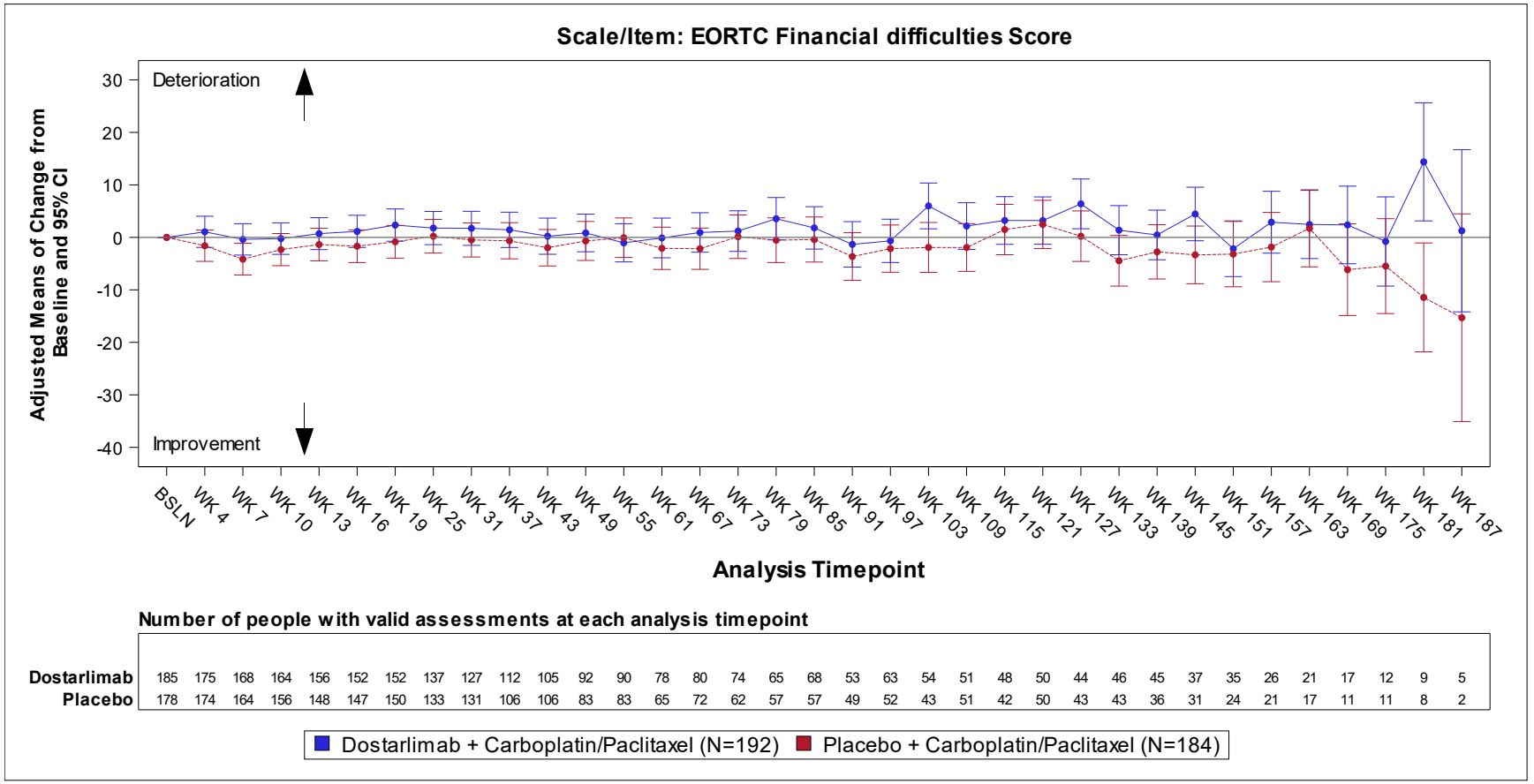


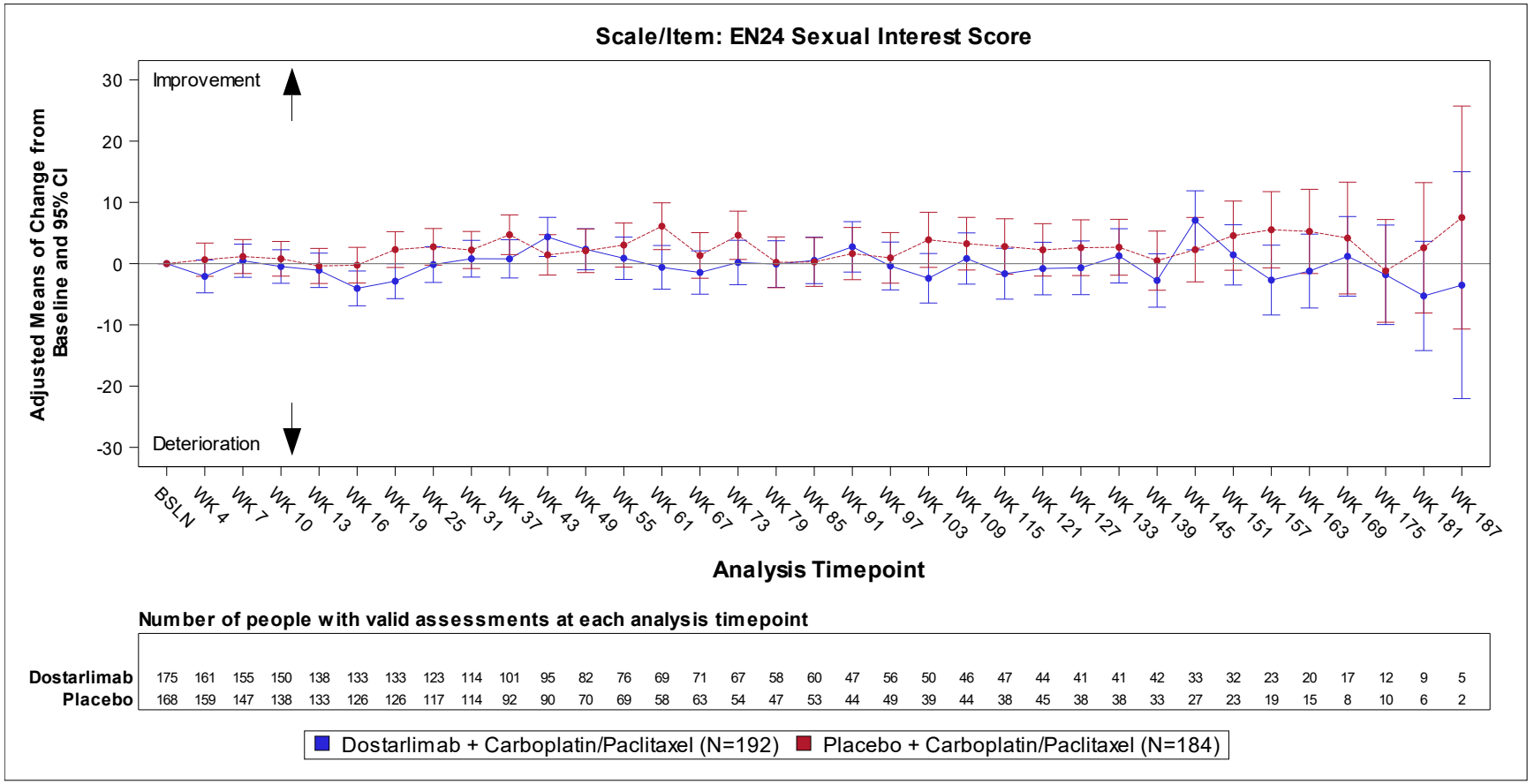
CI = Confidence Intervals, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Analysis timepoints with less than 2 subjects in either of the treatment arms were excluded from analysis

Program: f_2_0802_q30_mmrm.sas, Output: f_2_0802_q30_mmrm.rtf, Generated on: 14AUG2024 12:05, Data Cutoff Date: 22SEP2023

Figure 2.1402 EORTC-QLQ-EN24 Domain Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



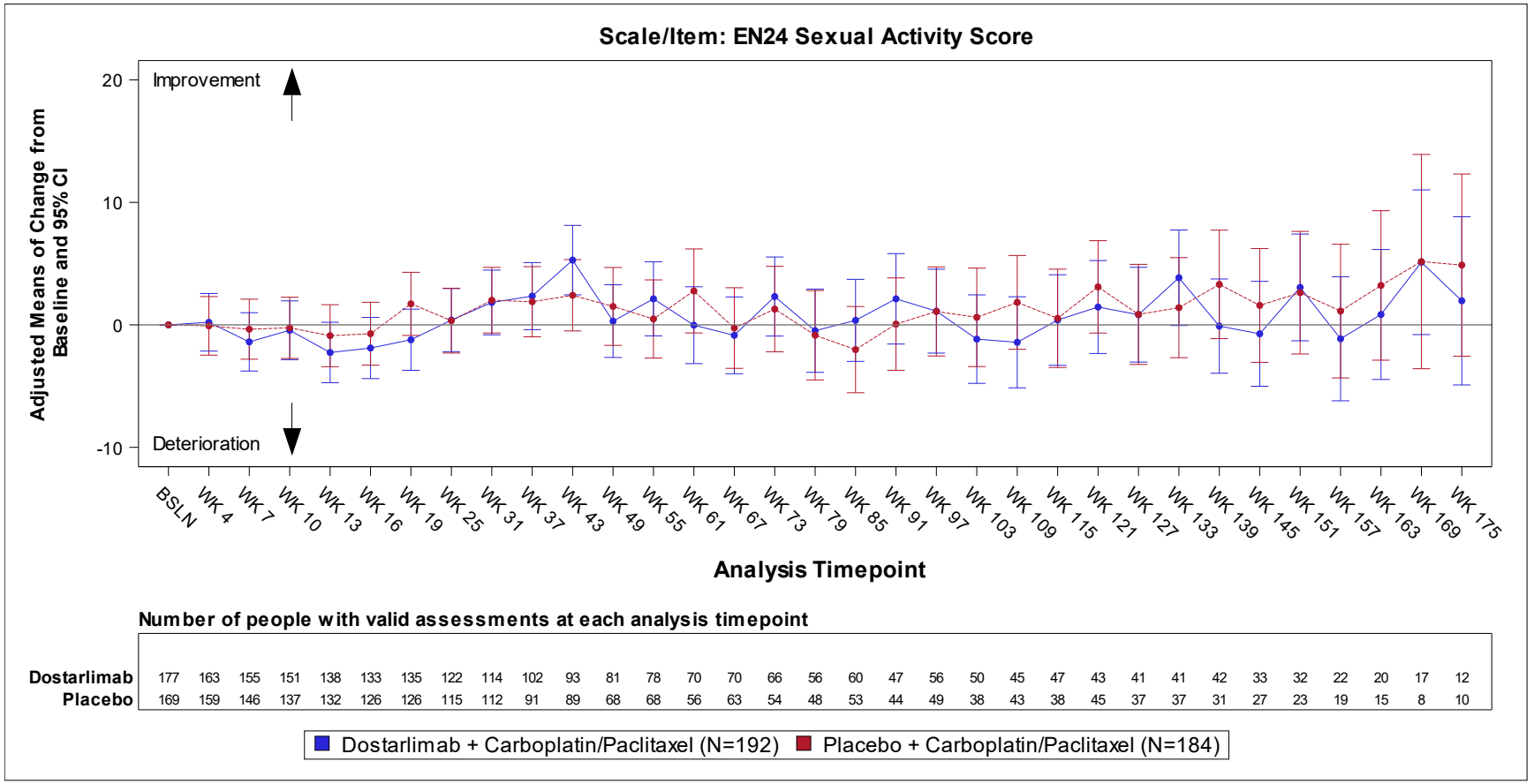
CI = Confidence Intervals, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis

Program: f_2_1402_en24_mmrm.sas, Output: f_2_1402_en24_mmrm.rtf, Generated on: 08AUG2024 11:27, Data Cutoff Date: 22SEP2023

Figure 2.1402 EORTC-QLQ-EN24 Domain Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



CI = Confidence Intervals, Only patients who have a baseline assessment are included.

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Note: Analysis timepoints with less than 7 subjects in either of the treatment arms were excluded from analysis

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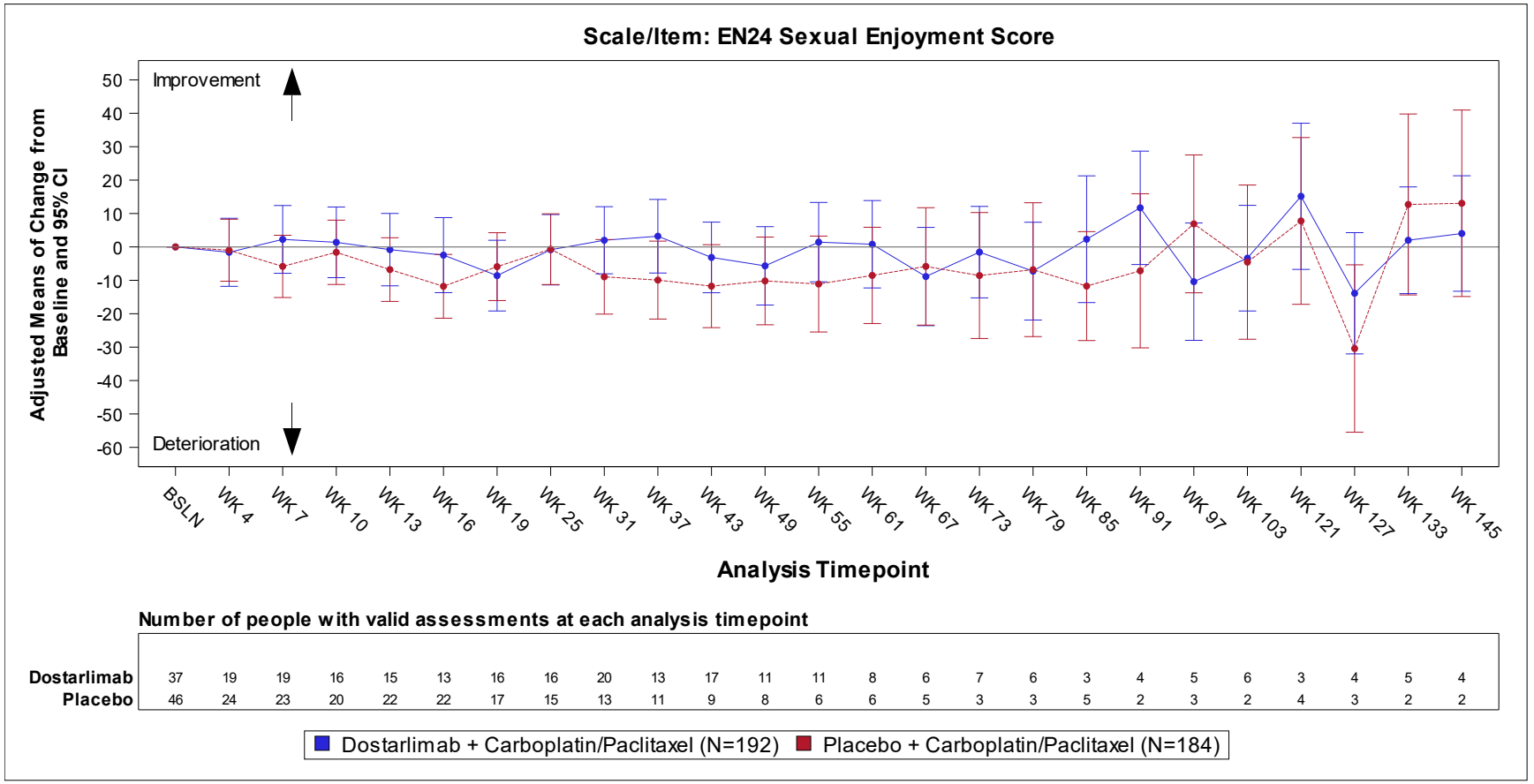
Figure 2.1402 EORTC-QLQ-EN24 Domain Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



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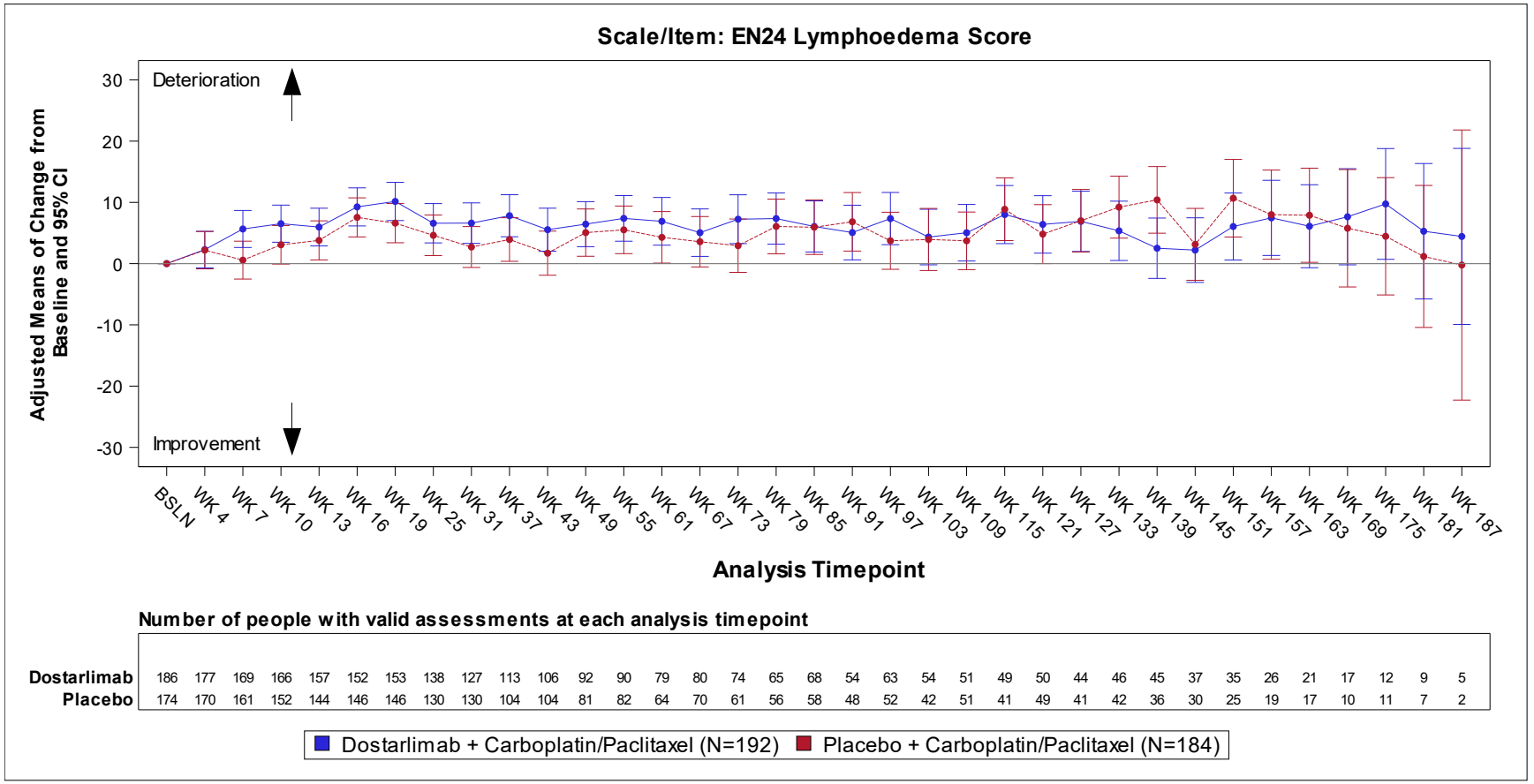

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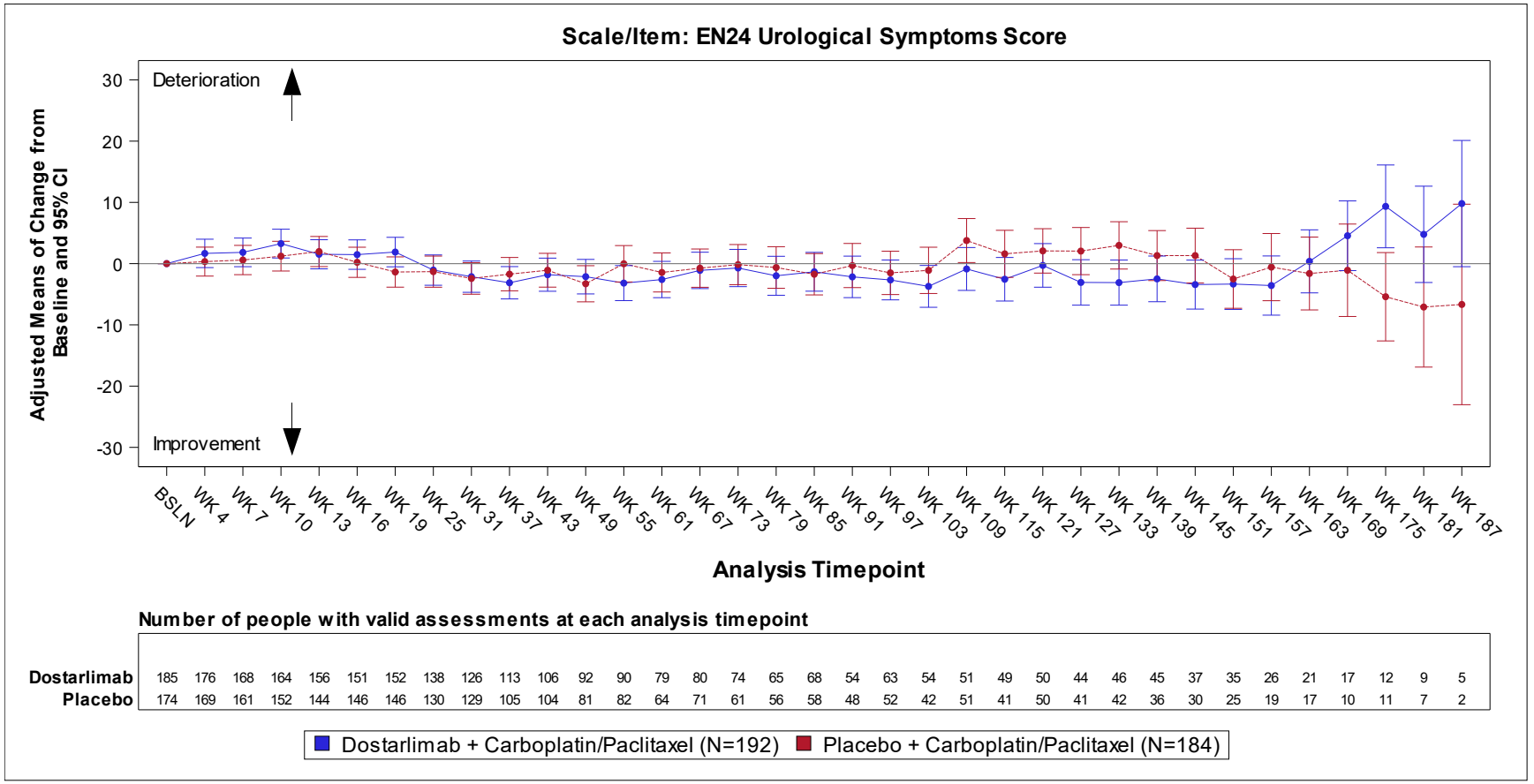

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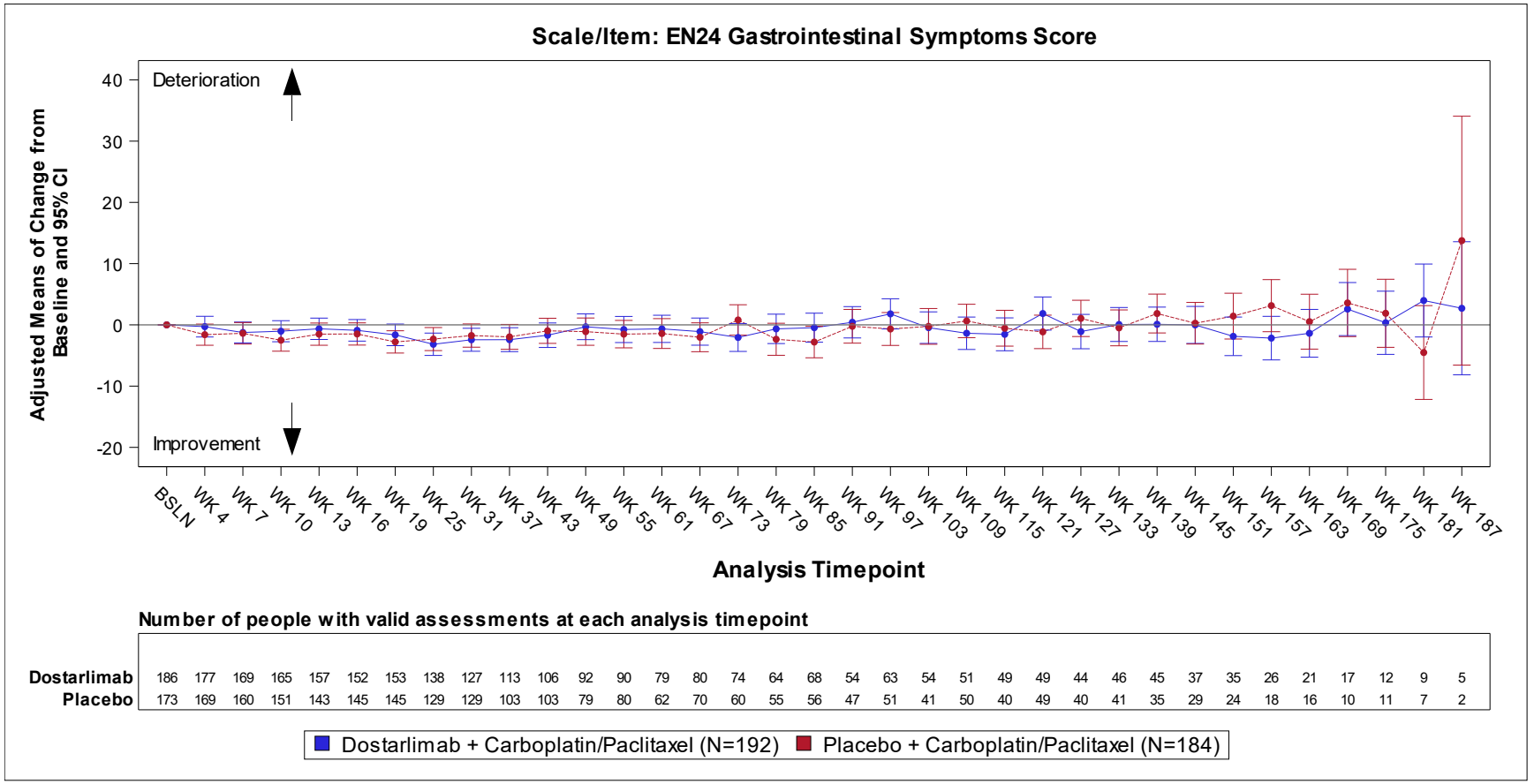

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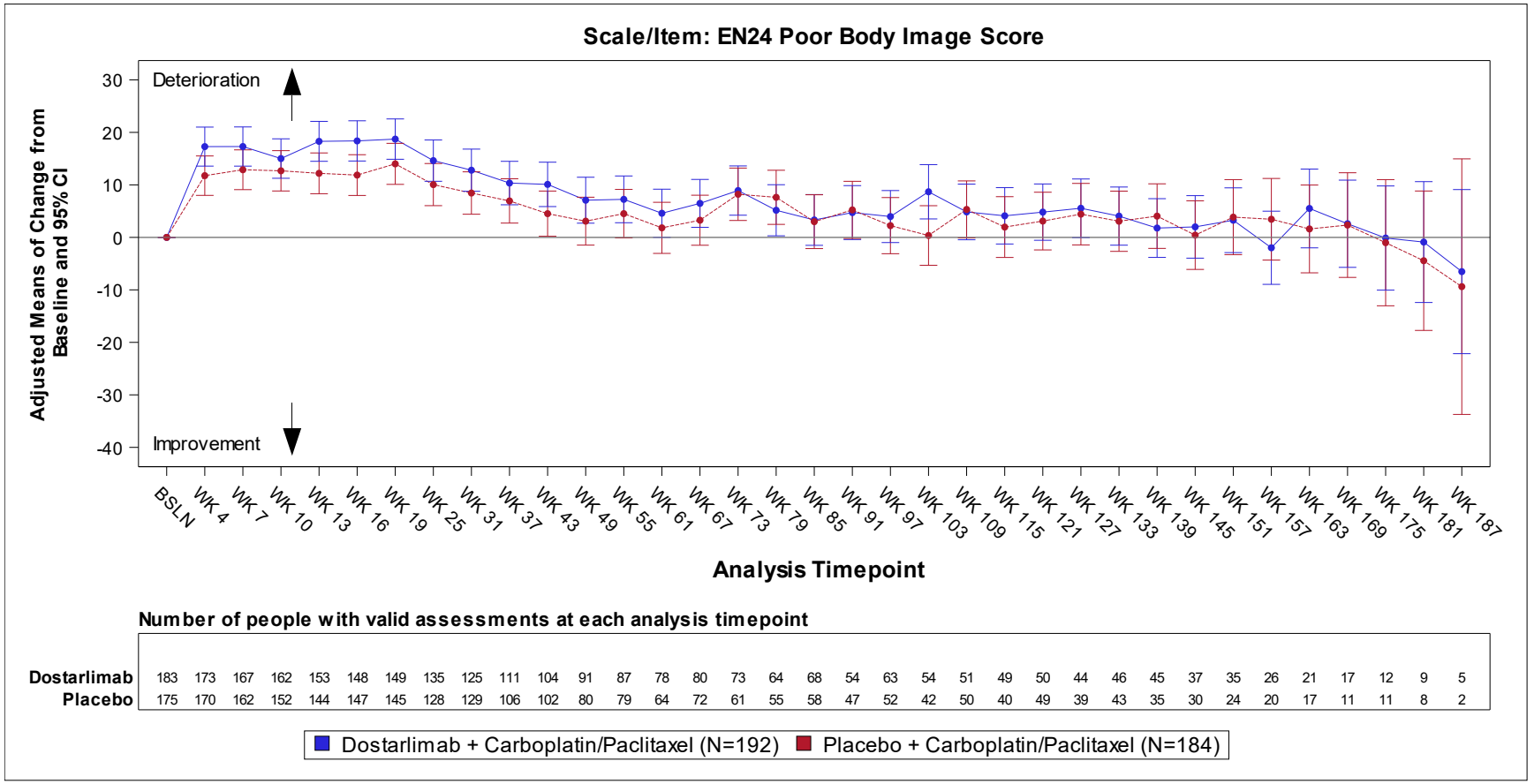

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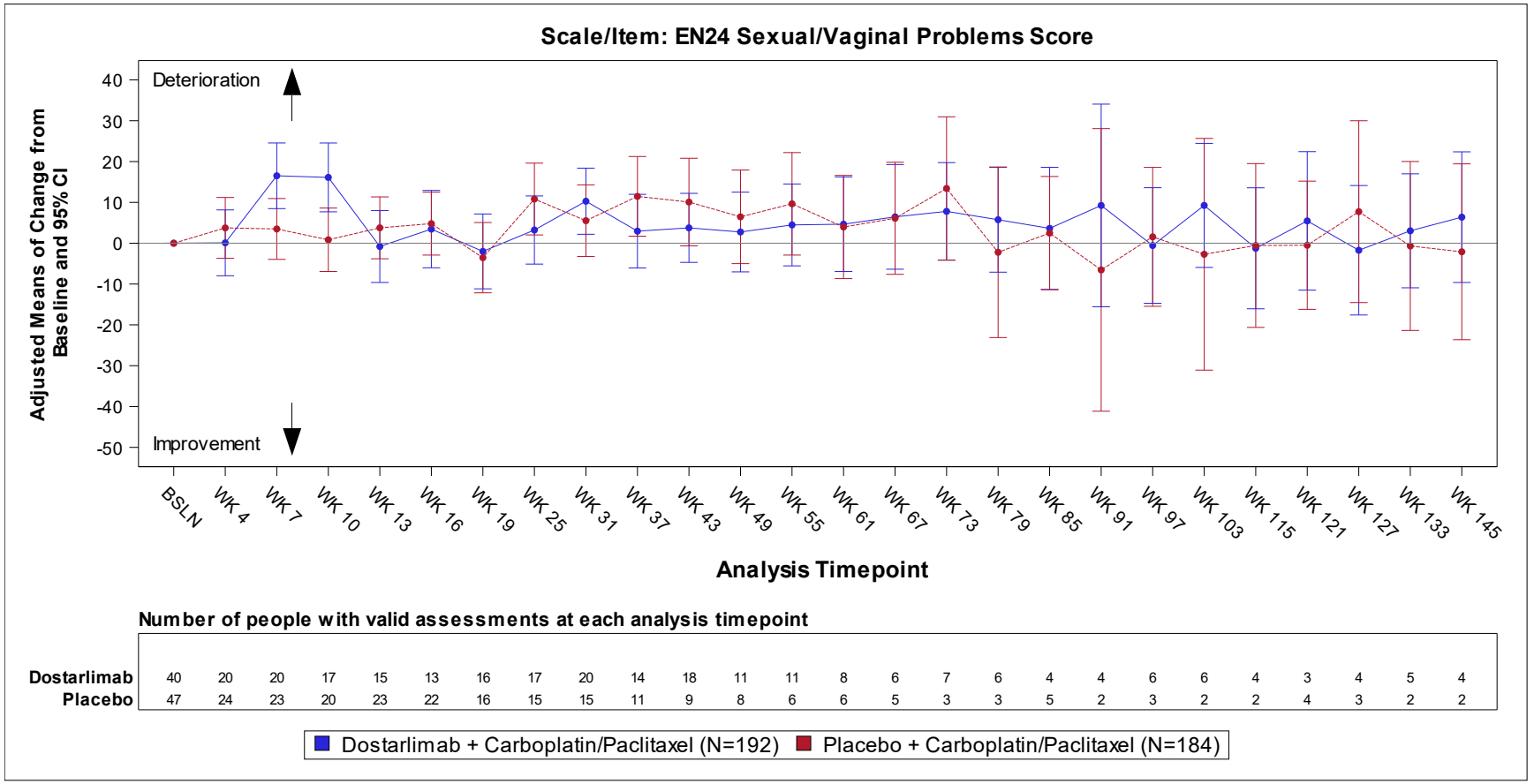

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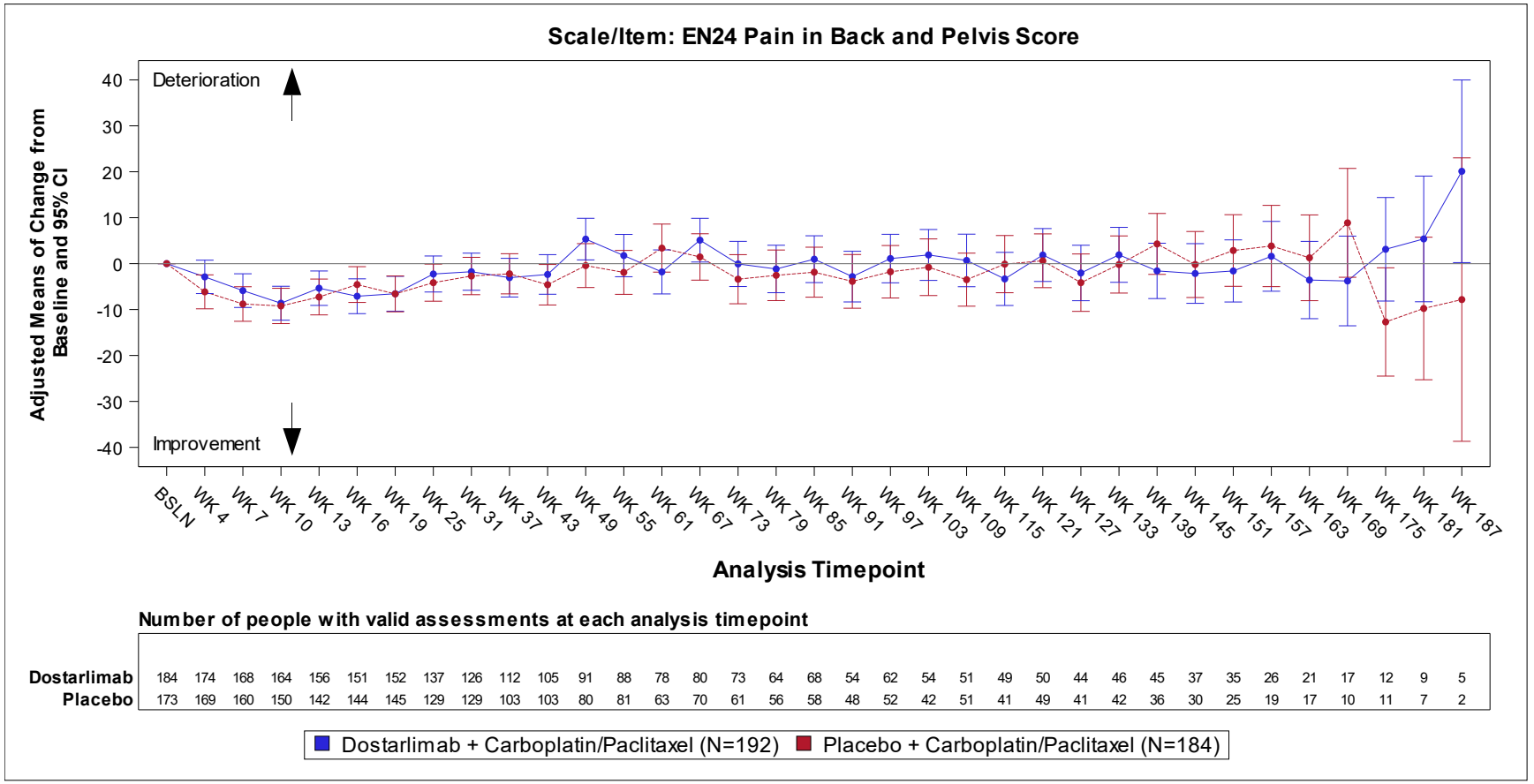

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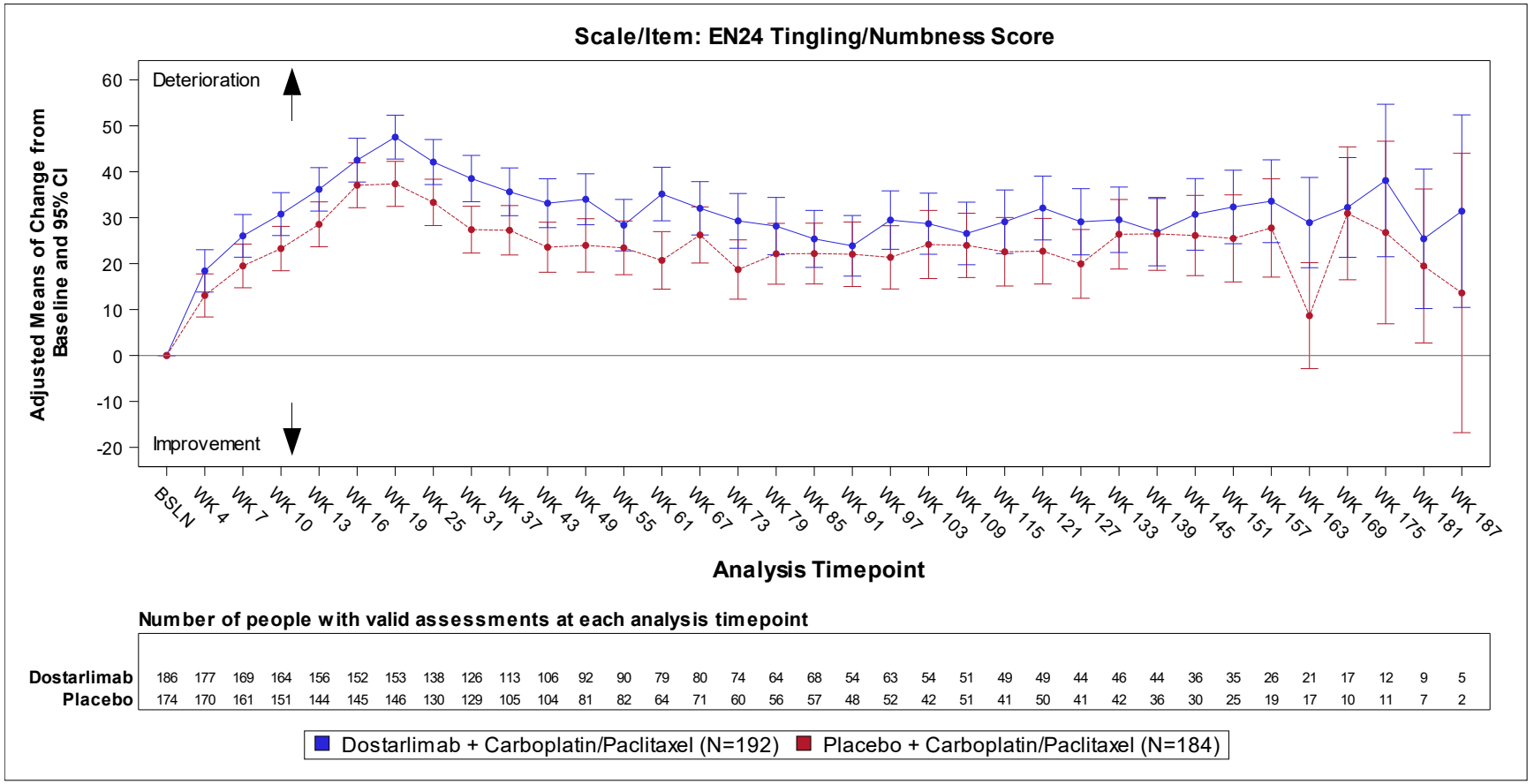
Figure 2.1402 EORTC-QLQ-EN24 Domain Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



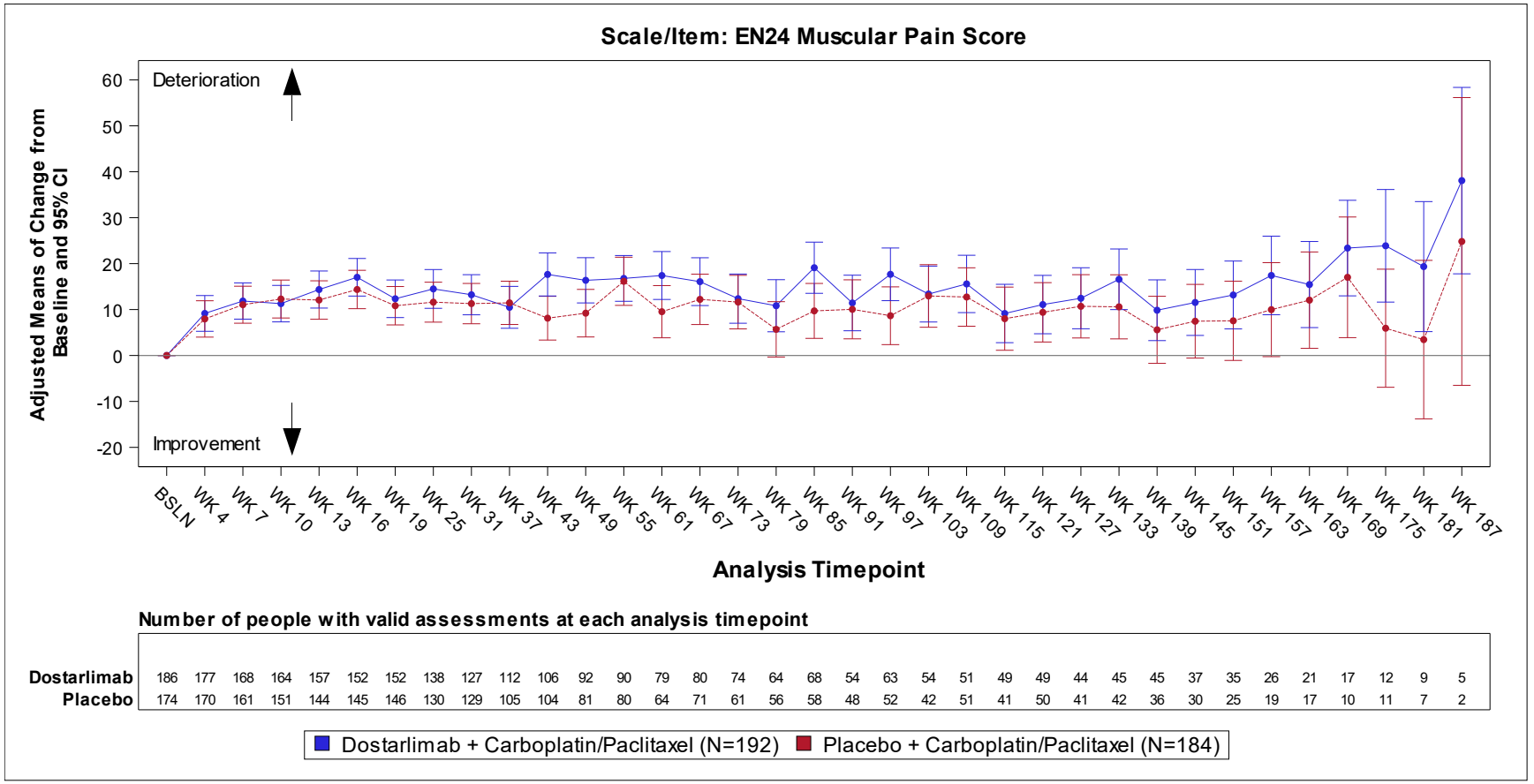
CI = Confidence Intervals, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis

Program: f_2_1402_en24_mmrm.sas, Output: f_2_1402_en24_mmrm.rtf, Generated on: 08AUG2024 11:27, Data Cutoff Date: 22SEP2023

Figure 2.1402 EORTC-QLQ-EN24 Domain Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



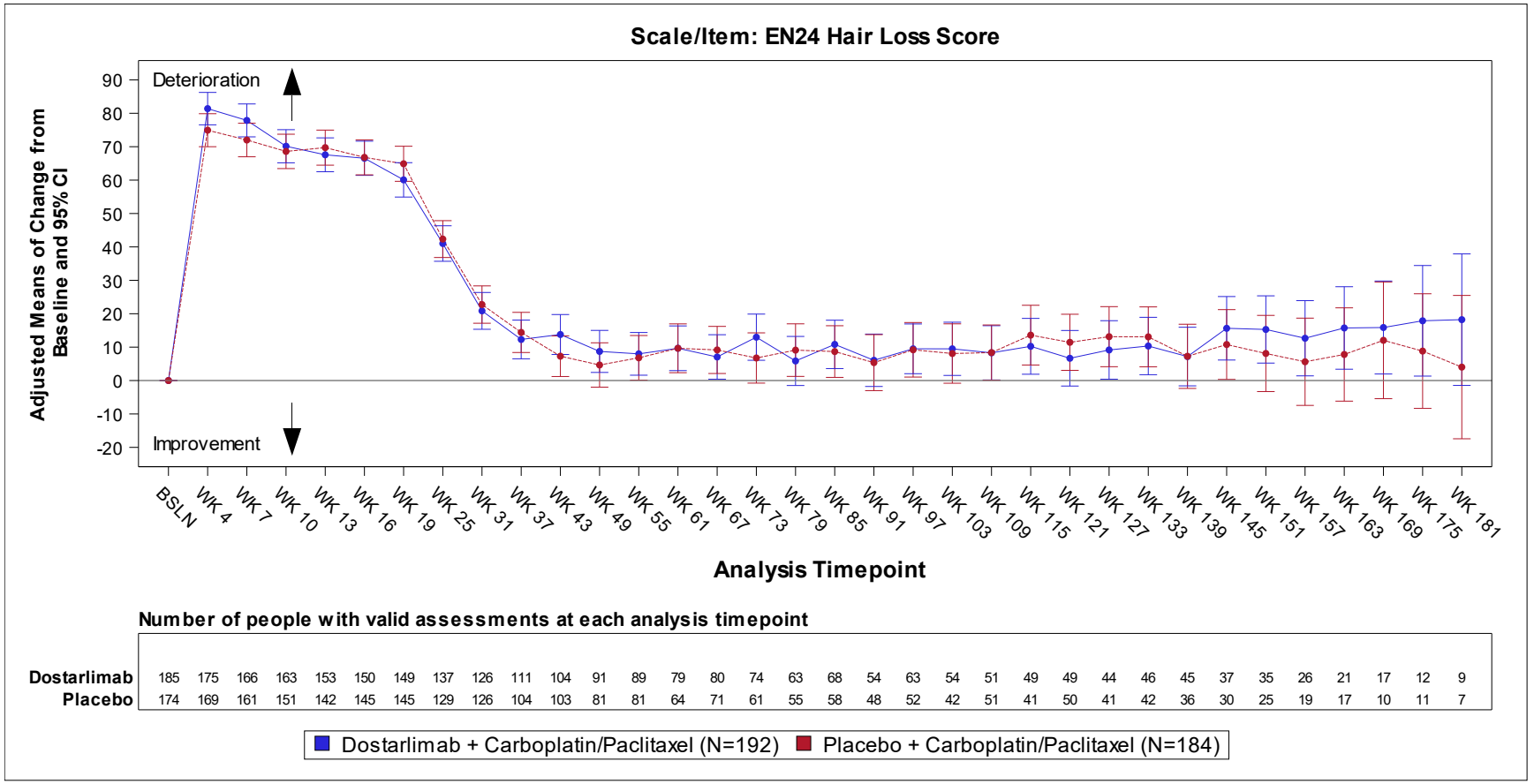
CI = Confidence Intervals, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis

Program: f_2_1402_en24_mmrm.sas, Output: f_2_1402_en24_mmrm.rtf, Generated on: 08AUG2024 11:27, Data Cutoff Date: 22SEP2023

Figure 2.1402 EORTC-QLQ-EN24 Domain Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



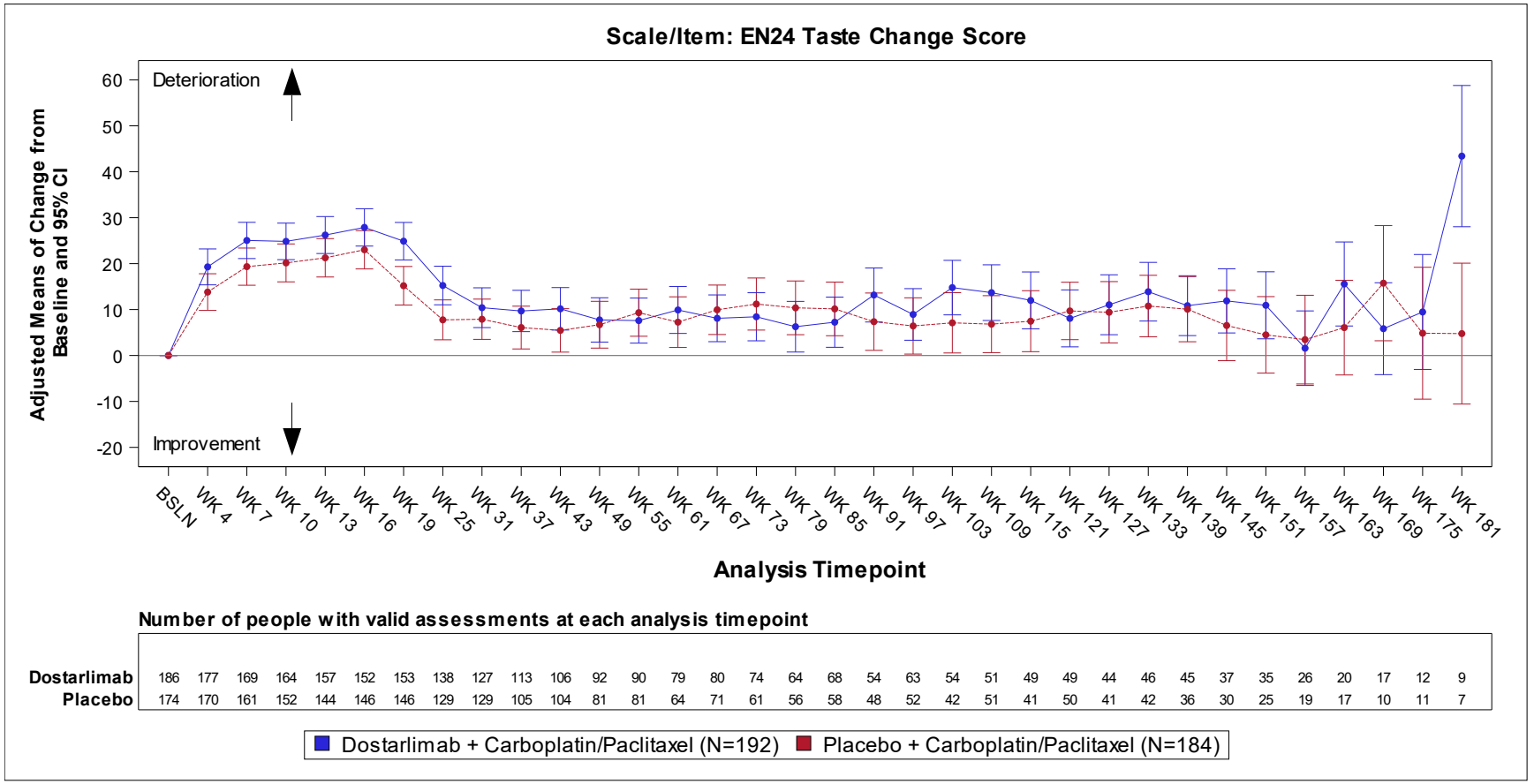
CI = Confidence Intervals, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis

Program: f_2_1402_en24_mmrm.sas, Output: f_2_1402_en24_mmrm.rtf, Generated on: 08AUG2024 11:27, Data Cutoff Date: 22SEP2023

Figure 2.1402 EORTC-QLQ-EN24 Domain Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



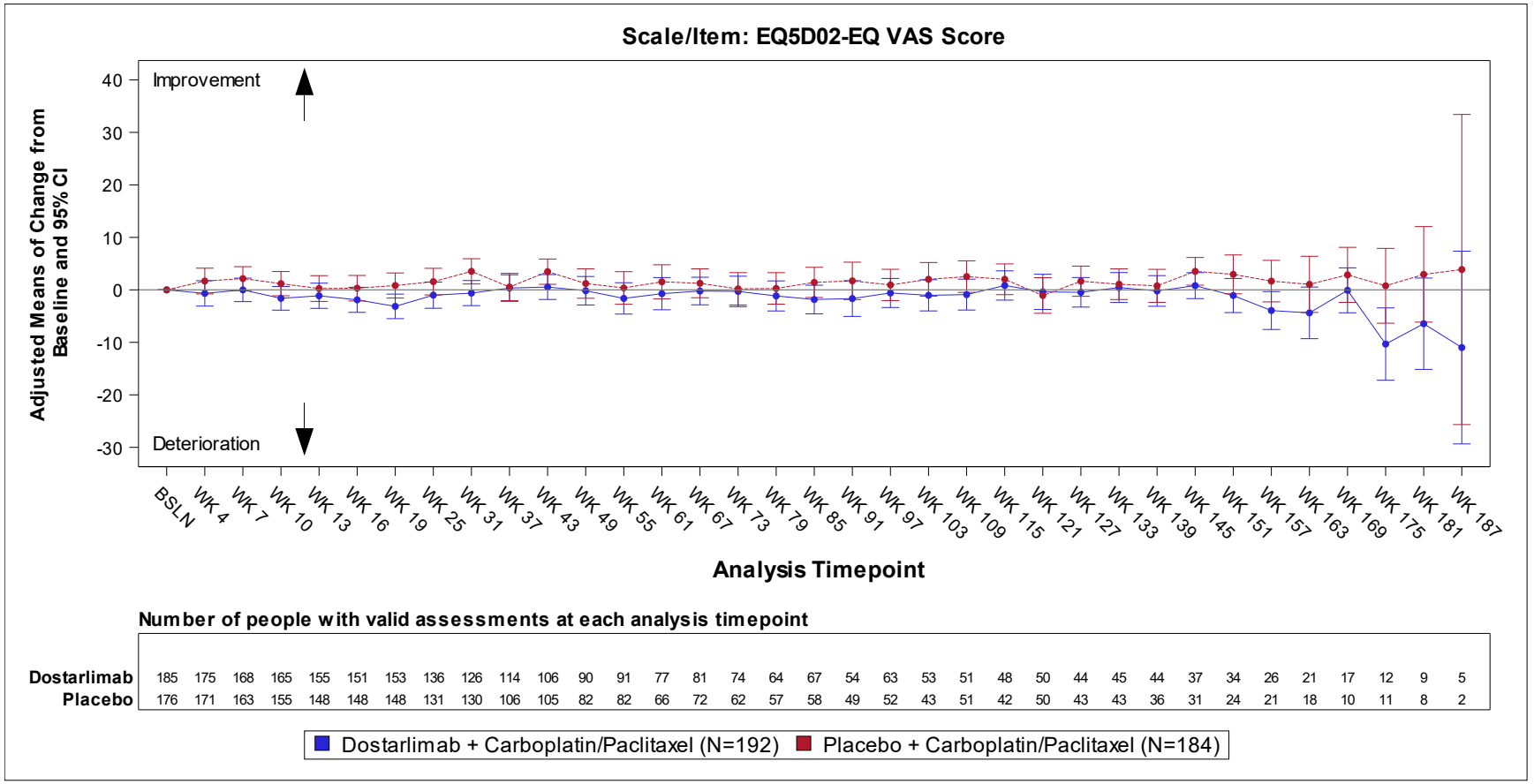
CI = Confidence Intervals, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Analysis timepoints with less than 3 subjects in either of the treatment arms were excluded from analysis

Program: f_2_1402_en24_mmrm.sas, Output: f_2_1402_en24_mmrm.rtf, Generated on: 08AUG2024 11:27, Data Cutoff Date: 22SEP2023

Figure 2.2002 EQ-5D-5L Visual Analogue Scores: Adjusted Mean Change from Baseline and 95% Confidence Intervals (ITT Analysis Set): MMRp/MSS Subjects



CI = Confidence Intervals, Only patients who have a baseline assessment are included.

Note: Adjusted means, 95% CI and p-values from a mixed model for repeated measures (MMRM) with treatment, analysis timepoint, and treatment-by-analysis timepoint interaction as fixed effects, baseline as a continuous covariate along with baseline-by-analysis timepoint interaction (fixed effects), and subject is a random effect. An AR(1) covariance matrix is used to model the within subject variance and the Kenward-Roger approximation is used to estimate the degrees of freedom.

Note: Analysis timepoints with less than 1 subjects in either of the treatment arms were excluded from analysis

Program: f_2_2002_eq5d_mmrm.sas, Output: f_2_2002_eq5d_mmrm.rtf, Generated on: 07AUG2024 17:02, Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	178
		Mean (std)	68.0 (20.42)	70.6 (20.06)
		Median	67.0	75.0
		Q1, Q3	50.0, 83.0	58.0, 83.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	179	176
		Mean (std)	70.2 (17.33)	70.3 (19.43)
		Median	67.0	75.0
		Q1, Q3	58.0, 83.0	58.0, 83.0
		Min, Max	17, 100	17, 100
	Change from BL	n	177	174
		Mean (std)	1.7 (16.46)	-0.2 (19.69)
		Median	0	0
		Q1, Q3	-8.0, 9.0	-16.0, 9.0
		Min, Max	-50, 75	-59, 66

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	167
		Mean (std)	69.8 (18.99)	72.7 (18.86)
		Median	67.0	75.0
		Q1, Q3	58.0, 83.0	58.0, 83.0
		Min, Max	0, 100	8, 100
	Change from BL	n	169	165
		Mean (std)	0.6 (19.77)	2.6 (19.39)
		Median	0	0
		Q1, Q3	-9.0, 9.0	-8.0, 16.0
		Min, Max	-66, 83	-67, 67
Week 10	Actual	n	169	158
		Mean (std)	69.0 (18.91)	70.4 (19.87)
		Median	67.0	67.0
		Q1, Q3	58.0, 83.0	58.0, 83.0
		Min, Max	17, 100	0, 100
	Change from BL	n	166	156
		Mean (std)	-0.3 (20.15)	-0.3 (21.61)
		Median	0	0
		Q1, Q3	-16.0, 9.0	-16.0, 16.0
		Min, Max	-58, 83	-92, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	151
		Mean (std)	67.6 (18.98)	70.5 (18.85)
		Median	67.0	75.0
		Q1, Q3	58.0, 83.0	58.0, 83.0
		Min, Max	0, 100	17, 100
	Change from BL	n	157	149
		Mean (std)	-1.2 (23.05)	-0.6 (20.28)
		Median	0	0
		Q1, Q3	-16.0, 9.0	-16.0, 16.0
		Min, Max	-84, 83	-58, 67
Week 16	Actual	n	154	150
		Mean (std)	65.6 (19.68)	69.7 (20.33)
		Median	67.0	75.0
		Q1, Q3	50.0, 83.0	58.0, 83.0
		Min, Max	8, 100	0, 100
	Change from BL	n	152	148
		Mean (std)	-4.0 (23.92)	-1.5 (22.22)
		Median	0	0
		Q1, Q3	-17.0, 8.0	-16.0, 9.0
		Min, Max	-67, 83	-66, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	66.8 (18.00)	69.9 (18.85)
		Median	67.0	67.0
		Q1, Q3	56.0, 83.0	58.0, 83.0
		Min, Max	8, 100	17, 100
	Change from BL	n	153	150
		Mean (std)	-2.8 (21.91)	-1.3 (20.97)
		Median	0	0
		Q1, Q3	-17.0, 8.0	-16.0, 9.0
		Min, Max	-50, 83	-58, 67
Week 25	Actual	n	140	135
		Mean (std)	68.6 (19.09)	73.0 (20.00)
		Median	67.0	83.0
		Q1, Q3	50.0, 83.0	67.0, 83.0
		Min, Max	17, 100	0, 100
	Change from BL	n	138	133
		Mean (std)	-0.3 (21.83)	1.1 (20.29)
		Median	0	0
		Q1, Q3	-16.0, 9.0	-9.0, 16.0
		Min, Max	-67, 75	-58, 75

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	133
		Mean (std)	71.9 (18.99)	73.2 (18.28)
		Median	75.0	83.0
		Q1, Q3	58.5, 83.0	67.0, 83.0
		Min, Max	17, 100	17, 100
	Change from BL	n	127	132
		Mean (std)	1.0 (22.32)	0.5 (18.95)
		Median	0	0
		Q1, Q3	-9.0, 16.0	-9.0, 9.0
		Min, Max	-50, 100	-50, 75
Week 37	Actual	n	115	108
		Mean (std)	74.1 (15.88)	74.7 (16.65)
		Median	79.5	83.0
		Q1, Q3	67.0, 83.0	67.0, 83.0
		Min, Max	17, 100	42, 100
	Change from BL	n	113	107
		Mean (std)	3.9 (21.81)	0.5 (19.92)
		Median	0	0
		Q1, Q3	-9.0, 17.0	-16.0, 16.0
		Min, Max	-58, 83	-58, 58

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	106	107
		Mean (std)	74.4 (17.86)	73.5 (15.91)
		Median	83.0	83.0
		Q1, Q3	67.0, 83.0	67.0, 83.0
		Min, Max	17, 100	33, 100
	Change from BL	n	105	106
		Mean (std)	2.3 (22.87)	-0.7 (19.20)
		Median	0	0
		Q1, Q3	-9.0, 16.0	-16.0, 8.0
		Min, Max	-75, 92	-50, 58
Week 49	Actual	n	94	83
		Mean (std)	72.6 (19.62)	73.9 (17.50)
		Median	83.0	75.0
		Q1, Q3	67.0, 83.0	67.0, 83.0
		Min, Max	17, 100	17, 100
	Change from BL	n	92	83
		Mean (std)	1.9 (22.68)	0.2 (20.36)
		Median	0	0
		Q1, Q3	-12.5, 16.0	-16.0, 9.0
		Min, Max	-50, 100	-75, 58

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	92	84
		Mean (std)	72.0 (17.27)	70.1 (17.71)
		Median	75.0	67.0
		Q1, Q3	58.0, 83.0	58.0, 83.0
		Min, Max	17, 100	17, 100
	Change from BL	n	90	83
		Mean (std)	0.7 (22.49)	-3.7 (22.99)
		Median	0	0
		Q1, Q3	-9.0, 16.0	-17.0, 8.0
		Min, Max	-83, 92	-83, 58
Week 61	Actual	n	80	65
		Mean (std)	72.4 (16.36)	74.2 (19.25)
		Median	75.0	75.0
		Q1, Q3	58.3, 83.0	67.0, 83.0
		Min, Max	33, 100	17, 100
	Change from BL	n	78	65
		Mean (std)	0.4 (22.15)	0.6 (22.49)
		Median	0	0
		Q1, Q3	-9.0, 8.0	-16.0, 17.0
		Min, Max	-67, 100	-50, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	71.5 (18.99)	75.2 (16.70)
		Median	75.0	83.0
		Q1, Q3	67.0, 83.0	67.0, 83.0
		Min, Max	17, 100	8, 100
	Change from BL	n	80	72
		Mean (std)	0 (23.59)	0.3 (22.00)
		Median	0	0
		Q1, Q3	-16.0, 9.0	-16.0, 12.5
		Min, Max	-50, 100	-75, 58
Week 73	Actual	n	76	62
		Mean (std)	72.7 (15.63)	69.9 (18.11)
		Median	75.0	67.0
		Q1, Q3	62.5, 83.0	58.0, 83.0
		Min, Max	25, 100	33, 100
	Change from BL	n	74	62
		Mean (std)	1.2 (24.36)	-3.7 (21.52)
		Median	0	0
		Q1, Q3	-16.0, 16.0	-17.0, 8.0
		Min, Max	-50, 100	-67, 59

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	75.5 (17.53)	73.9 (19.32)
		Median	83.0	83.0
		Q1, Q3	67.0, 83.0	67.0, 83.0
		Min, Max	33, 100	17, 100
	Change from BL	n	65	57
		Mean (std)	2.7 (20.57)	-0.9 (22.64)
		Median	0	0
		Q1, Q3	-8.0, 16.0	-16.0, 8.0
		Min, Max	-42, 83	-50, 66
Week 85	Actual	n	70	58
		Mean (std)	73.1 (16.88)	72.5 (17.67)
		Median	75.0	75.0
		Q1, Q3	67.0, 83.0	67.0, 83.0
		Min, Max	17, 100	25, 100
	Change from BL	n	68	58
		Mean (std)	3.4 (22.97)	-1.0 (19.83)
		Median	0	0
		Q1, Q3	-9.0, 17.0	-16.0, 9.0
		Min, Max	-66, 67	-50, 59

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	50
		Mean (std)	73.4 (19.58)	71.1 (20.05)
		Median	83.0	71.0
		Q1, Q3	67.0, 83.0	58.5, 83.0
		Min, Max	0, 100	8, 100
	Change from BL	n	53	49
		Mean (std)	3.5 (26.76)	-5.1 (26.29)
		Median	0	0
		Q1, Q3	-16.0, 17.0	-17.0, 8.0
		Min, Max	-100, 83	-92, 50
Week 97	Actual	n	65	52
		Mean (std)	72.8 (18.21)	69.7 (18.61)
		Median	83.0	75.0
		Q1, Q3	67.0, 83.0	58.0, 83.0
		Min, Max	17, 100	17, 100
	Change from BL	n	63	52
		Mean (std)	1.6 (25.41)	-2.1 (21.03)
		Median	0	0
		Q1, Q3	-16.0, 17.0	-16.5, 9.0
		Min, Max	-66, 83	-59, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	72.8 (17.67)	74.0 (16.12)
		Median	75.0	75.0
		Q1, Q3	67.0, 83.0	67.0, 83.0
		Min, Max	17, 100	42, 100
	Change from BL	n	54	43
		Mean (std)	5.0 (23.29)	-0.2 (20.56)
		Median	0	0
		Q1, Q3	-9.0, 17.0	-16.0, 9.0
		Min, Max	-50, 83	-33, 67
Week 109	Actual	n	52	51
		Mean (std)	72.0 (18.81)	73.7 (16.55)
		Median	83.0	75.0
		Q1, Q3	67.0, 83.0	67.0, 83.0
		Min, Max	17, 100	42, 100
	Change from BL	n	51	51
		Mean (std)	1.3 (23.46)	0.5 (20.91)
		Median	0	0
		Q1, Q3	-16.0, 16.0	-16.0, 16.0
		Min, Max	-66, 83	-33, 58

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	74.6 (18.34)	69.9 (22.25)
		Median	83.0	75.0
		Q1, Q3	67.0, 83.0	50.0, 83.0
		Min, Max	0, 100	17, 100
	Change from BL	n	49	42
		Mean (std)	5.6 (26.21)	-3.5 (21.98)
		Median	0	0
		Q1, Q3	-8.0, 17.0	-17.0, 8.0
		Min, Max	-100, 83	-50, 50
Week 121	Actual	n	51	50
		Mean (std)	72.5 (19.05)	68.8 (22.52)
		Median	75.0	71.0
		Q1, Q3	58.0, 83.0	50.0, 83.0
		Min, Max	8, 100	17, 100
	Change from BL	n	50	50
		Mean (std)	0.7 (17.36)	-4.5 (23.76)
		Median	0	0
		Q1, Q3	-8.0, 8.0	-17.0, 8.5
		Min, Max	-50, 42	-66, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	43
		Mean (std)	74.4 (17.12)	70.5 (19.72)
		Median	83.0	75.0
		Q1, Q3	67.0, 83.0	50.0, 83.0
		Min, Max	33, 100	17, 100
	Change from BL	n	44	43
		Mean (std)	7.7 (23.82)	-2.3 (22.11)
		Median	8.0	0
		Q1, Q3	0, 17.0	-17.0, 16.0
		Min, Max	-50, 83	-50, 50
Week 133	Actual	n	48	43
		Mean (std)	75.7 (17.11)	71.7 (19.83)
		Median	75.0	75.0
		Q1, Q3	67.0, 83.0	50.0, 83.0
		Min, Max	33, 100	25, 100
	Change from BL	n	46	43
		Mean (std)	5.5 (20.92)	-1.0 (22.01)
		Median	0	0
		Q1, Q3	-8.0, 17.0	-17.0, 16.0
		Min, Max	-50, 67	-58, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	74.1 (17.08)	68.1 (20.08)
		Median	75.0	71.0
		Q1, Q3	67.0, 83.0	50.0, 83.0
		Min, Max	33, 100	29, 100
	Change from BL	n	45	36
		Mean (std)	6.8 (22.27)	-4.8 (25.38)
		Median	0	0
		Q1, Q3	-8.0, 17.0	-25.0, 8.0
		Min, Max	-25, 83	-67, 59
Week 145	Actual	n	38	31
		Mean (std)	75.3 (17.39)	79.7 (14.55)
		Median	83.0	83.0
		Q1, Q3	67.0, 83.0	67.0, 83.0
		Min, Max	33, 100	50, 100
	Change from BL	n	37	31
		Mean (std)	2.2 (21.50)	3.4 (18.91)
		Median	0	0
		Q1, Q3	-16.0, 17.0	-16.0, 16.0
		Min, Max	-42, 42	-17, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	72.0 (20.00)	74.8 (17.88)
		Median	75.0	75.0
		Q1, Q3	67.0, 83.0	67.0, 83.0
		Min, Max	17, 100	33, 100
	Change from BL	n	35	24
		Mean (std)	3.3 (24.36)	0.9 (27.03)
		Median	0	0
		Q1, Q3	-16.0, 17.0	-17.0, 17.0
		Min, Max	-50, 83	-50, 59
Week 157	Actual	n	26	21
		Mean (std)	74.1 (18.42)	70.2 (17.07)
		Median	83.0	67.0
		Q1, Q3	67.0, 83.0	66.5, 83.0
		Min, Max	33, 100	33, 100
	Change from BL	n	26	21
		Mean (std)	-2.1 (24.84)	0 (20.55)
		Median	0	0
		Q1, Q3	-16.0, 9.0	-16.0, 16.0
		Min, Max	-50, 83	-41, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	69.7 (20.03)	76.9 (17.02)
		Median	83.0	83.0
		Q1, Q3	50.0, 83.0	67.0, 83.0
		Min, Max	17, 100	33, 100
	Change from BL	n	21	17
		Mean (std)	1.9 (24.53)	3.5 (25.24)
		Median	0	0
		Q1, Q3	0, 8.0	-16.0, 16.0
		Min, Max	-66, 67	-50, 50
Week 169	Actual	n	17	11
		Mean (std)	74.4 (14.53)	74.8 (19.08)
		Median	83.0	83.0
		Q1, Q3	67.0, 83.0	58.0, 83.0
		Min, Max	33, 92	33, 100
	Change from BL	n	17	11
		Mean (std)	2.3 (23.59)	-4.7 (23.02)
		Median	0	0
		Q1, Q3	-9.0, 16.0	-25.0, 16.0
		Min, Max	-34, 67	-50, 25

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	63.8 (19.85)	71.3 (13.54)
		Median	58.0	67.0
		Q1, Q3	50.0, 83.0	67.0, 83.0
		Min, Max	33, 100	50, 92
	Change from BL	n	12	11
		Mean (std)	-4.3 (23.39)	-9.0 (17.00)
		Median	-8.5	-9.0
		Q1, Q3	-17.0, 8.5	-16.0, 8.0
		Min, Max	-50, 33	-33, 17
Week 181	Actual	n	9	8
		Mean (std)	57.3 (34.95)	80.3 (17.73)
		Median	75.0	83.0
		Q1, Q3	42.0, 83.0	67.0, 96.0
		Min, Max	0, 100	50, 100
	Change from BL	n	9	8
		Mean (std)	-16.9 (45.11)	-2.0 (20.07)
		Median	-17.0	-4.5
		Q1, Q3	-25.0, 16.0	-16.0, 16.5
		Min, Max	-92, 41	-33, 25

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	60.0 (26.01)	75.0 (11.31)
		Median	58.0	75.0
		Q1, Q3	42.0, 67.0	67.0, 83.0
		Min, Max	33, 100	67, 83
	Change from BL	n	5	2
		Mean (std)	-5.0 (19.66)	-12.5 (4.95)
		Median	-8.0	-12.5
		Q1, Q3	-9.0, 9.0	-16.0, -9.0
		Min, Max	-34, 17	-16, -9
Week 193	Actual	n	1	0
		Mean (std)	83.0 (-)	
		Median	83.0	
		Q1, Q3	83.0, 83.0	
		Min, Max	83, 83	
	Change from BL	n	1	0
		Mean (std)	33.0 (-)	
		Median	33.0	
		Q1, Q3	33.0, 33.0	
		Min, Max	33, 33	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		92.0 (-)
		Median		92.0
		Q1, Q3		92.0, 92.0
		Min, Max		92, 92
	Change from BL	n	0	1
		Mean (std)		25.0 (-)
		Median		25.0
		Q1, Q3		25.0, 25.0
		Min, Max		25, 25
Week 205	Actual	n	0	1
		Mean (std)		92.0 (-)
		Median		92.0
		Q1, Q3		92.0, 92.0
		Min, Max		92, 92
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	43.0 (20.24)	46.5 (21.94)
		Median	42.0	50.0
		Q1, Q3	33.0, 58.0	33.0, 67.0
		Min, Max	0, 83	0, 92
	Change from BL	n	181	176
		Mean (std)	-25.5 (23.02)	-24.2 (25.01)
		Median	-25.0	-17.0
		Q1, Q3	-34.0, -16.0	-41.0, -9.0
		Min, Max	-100, 25	-92, 58
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	83.5 (13.93)	83.7 (14.92)
		Median	83.0	83.0
		Q1, Q3	75.0, 92.0	75.0, 100.0
		Min, Max	17, 100	25, 100
	Change from BL	n	181	176
		Mean (std)	15.1 (19.67)	13.1 (18.12)
		Median	9.0	16.0
		Q1, Q3	0, 25.0	0, 25.0
		Min, Max	-50, 100	-42, 75

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	185	178
		Mean (std)	78.7 (20.42)	78.8 (20.88)
		Median	87.0	80.0
		Q1, Q3	67.0, 93.0	67.0, 93.0
		Min, Max	13, 100	7, 100
Week 4	Actual	n	179	176
		Mean (std)	76.3 (21.18)	79.5 (19.44)
		Median	80.0	87.0
		Q1, Q3	67.0, 93.0	67.0, 93.0
		Min, Max	13, 100	20, 100
	Change from BL	n	176	174
		Mean (std)	-2.6 (15.57)	0.4 (12.52)
		Median	0	0
		Q1, Q3	-7.0, 6.0	-6.0, 7.0
		Min, Max	-74, 53	-47, 40

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	166
		Mean (std)	75.4 (20.72)	78.3 (19.85)
		Median	80.0	87.0
		Q1, Q3	63.5, 93.0	67.0, 93.0
		Min, Max	7, 100	13, 100
	Change from BL	n	169	164
		Mean (std)	-3.8 (16.33)	-0.9 (14.77)
		Median	0	0
		Q1, Q3	-13.0, 7.0	-7.0, 7.0
		Min, Max	-53, 60	-67, 53
Week 10	Actual	n	168	157
		Mean (std)	74.7 (21.02)	77.3 (20.81)
		Median	80.0	80.0
		Q1, Q3	67.0, 87.0	67.0, 93.0
		Min, Max	0, 100	7, 100
	Change from BL	n	165	155
		Mean (std)	-5.6 (19.32)	-2.9 (17.53)
		Median	-6.0	0
		Q1, Q3	-14.0, 0	-13.0, 7.0
		Min, Max	-80, 60	-80, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	150
		Mean (std)	73.3 (22.43)	74.6 (21.78)
		Median	80.0	80.0
		Q1, Q3	60.0, 87.0	67.0, 93.0
		Min, Max	0, 100	7, 100
	Change from BL	n	156	148
		Mean (std)	-5.9 (20.91)	-5.8 (17.21)
		Median	-6.0	0
		Q1, Q3	-20.0, 0	-13.0, 6.0
		Min, Max	-80, 67	-60, 40
Week 16	Actual	n	155	151
		Mean (std)	71.7 (23.36)	73.9 (23.34)
		Median	80.0	80.0
		Q1, Q3	60.0, 92.0	60.0, 93.0
		Min, Max	0, 100	0, 100
	Change from BL	n	151	149
		Mean (std)	-7.8 (24.59)	-7.1 (20.30)
		Median	-6.0	-6.0
		Q1, Q3	-20.0, 7.0	-14.0, 6.0
		Min, Max	-86, 60	-74, 60

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	151
		Mean (std)	71.8 (22.94)	74.4 (21.99)
		Median	79.0	80.0
		Q1, Q3	55.0, 87.0	60.0, 93.0
		Min, Max	0, 100	7, 100
	Change from BL	n	152	149
		Mean (std)	-8.9 (24.38)	-6.4 (19.59)
		Median	-6.0	-6.0
		Q1, Q3	-20.0, 0	-20.0, 7.0
		Min, Max	-80, 67	-73, 60
Week 25	Actual	n	140	134
		Mean (std)	74.2 (21.40)	77.3 (22.75)
		Median	80.0	87.0
		Q1, Q3	60.0, 93.0	67.0, 93.0
		Min, Max	13, 100	7, 100
	Change from BL	n	137	132
		Mean (std)	-6.4 (22.40)	-3.5 (20.00)
		Median	-6.0	0
		Q1, Q3	-20.0, 6.0	-13.0, 7.0
		Min, Max	-67, 60	-74, 54

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	128	133
		Mean (std)	74.8 (21.96)	77.1 (22.74)
		Median	80.0	80.0
		Q1, Q3	60.0, 93.0	67.0, 93.0
		Min, Max	0, 100	0, 100
	Change from BL	n	125	132
		Mean (std)	-5.6 (22.17)	-4.9 (19.44)
		Median	0	0
		Q1, Q3	-16.5, 6.0	-13.0, 6.5
		Min, Max	-80, 67	-69, 67
Week 37	Actual	n	116	106
		Mean (std)	81.5 (17.33)	80.2 (18.92)
		Median	87.0	87.0
		Q1, Q3	73.0, 93.0	73.0, 93.0
		Min, Max	13, 100	27, 100
	Change from BL	n	113	105
		Mean (std)	0.3 (18.70)	-1.8 (19.18)
		Median	0	0
		Q1, Q3	-7.0, 7.0	-13.0, 7.0
		Min, Max	-53, 67	-53, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	104	107
		Mean (std)	80.0 (18.72)	80.8 (18.79)
		Median	87.0	87.0
		Q1, Q3	73.0, 93.0	73.0, 93.0
		Min, Max	20, 100	0, 100
	Change from BL	n	102	106
		Mean (std)	-0.6 (17.87)	-2.0 (17.83)
		Median	0	0
		Q1, Q3	-13.0, 7.0	-8.0, 7.0
		Min, Max	-53, 67	-60, 54
Week 49	Actual	n	94	83
		Mean (std)	77.8 (21.05)	80.2 (18.73)
		Median	87.0	87.0
		Q1, Q3	67.0, 93.0	73.0, 93.0
		Min, Max	0, 100	13, 100
	Change from BL	n	92	83
		Mean (std)	-2.9 (19.51)	-0.6 (19.43)
		Median	0	0
		Q1, Q3	-13.0, 7.0	-13.0, 7.0
		Min, Max	-60, 60	-67, 60

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	91	84
		Mean (std)	79.9 (20.02)	77.4 (21.71)
		Median	87.0	87.0
		Q1, Q3	73.0, 93.0	67.0, 93.0
		Min, Max	0, 100	0, 100
	Change from BL	n	89	83
		Mean (std)	-2.8 (19.98)	-5.3 (22.83)
		Median	0	0
		Q1, Q3	-13.0, 6.0	-13.0, 7.0
		Min, Max	-86, 67	-93, 54
Week 61	Actual	n	80	64
		Mean (std)	79.2 (18.93)	81.2 (16.41)
		Median	87.0	87.0
		Q1, Q3	73.0, 93.0	73.0, 93.0
		Min, Max	0, 100	33, 100
	Change from BL	n	78	64
		Mean (std)	-1.2 (19.31)	-0.1 (19.73)
		Median	-6.0	0
		Q1, Q3	-13.0, 6.0	-13.0, 7.0
		Min, Max	-40, 67	-47, 54

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	76.5 (21.20)	80.4 (18.63)
		Median	83.5	87.0
		Q1, Q3	60.0, 93.0	67.0, 93.0
		Min, Max	27, 100	20, 100
	Change from BL	n	80	72
		Mean (std)	-5.1 (19.30)	-2.9 (18.61)
		Median	0	0
		Q1, Q3	-13.0, 0	-13.0, 3.0
		Min, Max	-53, 67	-60, 60
Week 73	Actual	n	74	62
		Mean (std)	77.8 (18.72)	78.3 (18.44)
		Median	80.0	80.0
		Q1, Q3	67.0, 87.0	67.0, 93.0
		Min, Max	7, 100	33, 100
	Change from BL	n	72	62
		Mean (std)	-4.1 (20.36)	-3.0 (21.60)
		Median	-3.0	0
		Q1, Q3	-13.0, 7.0	-13.0, 7.0
		Min, Max	-50, 67	-60, 60

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	79.1 (18.80)	78.8 (20.89)
		Median	87.0	87.0
		Q1, Q3	67.0, 93.0	67.0, 93.0
		Min, Max	27, 100	20, 100
	Change from BL	n	65	57
		Mean (std)	-2.8 (18.94)	-3.4 (23.09)
		Median	0	0
		Q1, Q3	-13.0, 6.0	-13.0, 7.0
		Min, Max	-47, 60	-54, 60
Week 85	Actual	n	70	58
		Mean (std)	75.4 (20.08)	79.4 (20.66)
		Median	73.0	87.0
		Q1, Q3	67.0, 93.0	67.0, 93.0
		Min, Max	20, 100	13, 100
	Change from BL	n	68	58
		Mean (std)	-4.2 (21.07)	-1.3 (22.85)
		Median	0	0
		Q1, Q3	-14.0, 10.0	-13.0, 7.0
		Min, Max	-73, 60	-47, 80

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	49
		Mean (std)	77.5 (19.75)	81.1 (18.12)
		Median	83.0	87.0
		Q1, Q3	67.0, 93.0	73.0, 93.0
		Min, Max	7, 100	33, 100
	Change from BL	n	53	48
		Mean (std)	-4.9 (20.35)	-1.1 (20.51)
		Median	-6.0	0
		Q1, Q3	-13.0, 6.0	-13.0, 7.0
		Min, Max	-60, 54	-34, 60
Week 97	Actual	n	65	52
		Mean (std)	76.5 (20.21)	80.0 (21.82)
		Median	80.0	87.0
		Q1, Q3	67.0, 93.0	67.0, 100.0
		Min, Max	20, 100	0, 100
	Change from BL	n	63	52
		Mean (std)	-5.7 (20.77)	-1.5 (22.45)
		Median	-6.0	0
		Q1, Q3	-20.0, 6.0	-13.0, 7.0
		Min, Max	-80, 54	-73, 60

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	76.4 (21.42)	80.6 (17.68)
		Median	80.0	87.0
		Q1, Q3	67.0, 93.0	70.0, 93.0
		Min, Max	13, 100	33, 100
	Change from BL	n	54	43
		Mean (std)	-2.1 (18.15)	-0.5 (18.85)
		Median	0	0
		Q1, Q3	-13.0, 7.0	-13.0, 7.0
		Min, Max	-46, 60	-40, 54
Week 109	Actual	n	52	51
		Mean (std)	78.0 (18.33)	81.0 (20.06)
		Median	81.5	87.0
		Q1, Q3	63.5, 93.0	73.0, 100.0
		Min, Max	33, 100	33, 100
	Change from BL	n	51	51
		Mean (std)	-2.8 (20.48)	-1.9 (19.04)
		Median	0	0
		Q1, Q3	-13.0, 7.0	-13.0, 7.0
		Min, Max	-53, 60	-40, 60

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	78.3 (20.22)	76.7 (24.43)
		Median	87.0	87.0
		Q1, Q3	60.0, 93.0	67.0, 93.0
		Min, Max	7, 100	7, 100
	Change from BL	n	49	42
		Mean (std)	-2.1 (17.77)	-5.8 (23.77)
		Median	0	-3.0
		Q1, Q3	-13.0, 7.0	-14.0, 7.0
		Min, Max	-40, 47	-80, 54
Week 121	Actual	n	51	49
		Mean (std)	78.2 (20.25)	77.2 (23.59)
		Median	87.0	87.0
		Q1, Q3	67.0, 93.0	60.0, 93.0
		Min, Max	13, 100	7, 100
	Change from BL	n	50	49
		Mean (std)	-4.8 (15.31)	-3.8 (21.13)
		Median	0	0
		Q1, Q3	-13.0, 0	-13.0, 7.0
		Min, Max	-53, 33	-60, 40

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	42
		Mean (std)	78.9 (19.38)	79.2 (23.63)
		Median	80.0	87.0
		Q1, Q3	73.0, 93.0	73.0, 100.0
		Min, Max	27, 100	7, 100
	Change from BL	n	44	42
		Mean (std)	-0.7 (17.47)	-2.6 (25.25)
		Median	-3.0	0
		Q1, Q3	-10.5, 6.5	-13.0, 7.0
		Min, Max	-33, 47	-80, 60
Week 133	Actual	n	48	43
		Mean (std)	78.6 (19.03)	78.4 (25.73)
		Median	87.0	87.0
		Q1, Q3	67.0, 96.5	67.0, 100.0
		Min, Max	33, 100	0, 100
	Change from BL	n	46	43
		Mean (std)	-4.3 (18.17)	-2.8 (25.40)
		Median	0	0
		Q1, Q3	-14.0, 7.0	-13.0, 7.0
		Min, Max	-54, 47	-80, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	76.5 (17.88)	76.5 (24.62)
		Median	83.5	85.0
		Q1, Q3	67.0, 87.0	67.0, 93.0
		Min, Max	33, 100	13, 100
	Change from BL	n	45	36
		Mean (std)	-3.2 (21.22)	-6.8 (23.84)
		Median	-7.0	0
		Q1, Q3	-14.0, 7.0	-18.5, 7.0
		Min, Max	-40, 54	-74, 60
Week 145	Actual	n	38	31
		Mean (std)	79.2 (19.54)	87.9 (16.33)
		Median	87.0	93.0
		Q1, Q3	73.0, 93.0	87.0, 100.0
		Min, Max	33, 100	27, 100
	Change from BL	n	37	31
		Mean (std)	-5.0 (19.90)	0.9 (18.24)
		Median	0	0
		Q1, Q3	-13.0, 6.0	-7.0, 7.0
		Min, Max	-53, 27	-53, 54

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	72.3 (24.76)	85.8 (15.20)
		Median	80.0	87.0
		Q1, Q3	56.5, 93.0	76.5, 100.0
		Min, Max	7, 100	40, 100
	Change from BL	n	35	24
		Mean (std)	-4.7 (19.91)	-0.3 (19.10)
		Median	-6.0	0
		Q1, Q3	-13.0, 7.0	-13.0, 3.5
		Min, Max	-73, 40	-40, 60
Week 157	Actual	n	26	21
		Mean (std)	77.5 (19.95)	78.0 (23.20)
		Median	87.0	87.0
		Q1, Q3	67.0, 93.0	73.0, 93.0
		Min, Max	27, 100	27, 100
	Change from BL	n	26	21
		Mean (std)	-9.6 (22.60)	-2.6 (22.07)
		Median	-13.0	0
		Q1, Q3	-26.0, 0	-13.0, 7.0
		Min, Max	-66, 54	-60, 47

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	75.9 (18.49)	86.1 (15.80)
		Median	73.0	87.0
		Q1, Q3	67.0, 93.0	80.0, 100.0
		Min, Max	40, 100	53, 100
	Change from BL	n	21	17
		Mean (std)	-5.7 (20.82)	2.2 (19.77)
		Median	-7.0	0
		Q1, Q3	-20.0, 0	-7.0, 0
		Min, Max	-40, 34	-27, 54
Week 169	Actual	n	17	11
		Mean (std)	74.8 (23.36)	85.1 (14.86)
		Median	87.0	87.0
		Q1, Q3	53.0, 93.0	73.0, 100.0
		Min, Max	33, 100	60, 100
	Change from BL	n	17	11
		Mean (std)	-4.7 (22.07)	-2.2 (14.13)
		Median	-7.0	0
		Q1, Q3	-20.0, 7.0	-17.0, 13.0
		Min, Max	-40, 40	-27, 14

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	72.8 (20.70)	86.5 (15.77)
		Median	73.0	92.0
		Q1, Q3	67.0, 86.5	73.0, 100.0
		Min, Max	20, 100	53, 100
	Change from BL	n	12	11
		Mean (std)	-8.9 (14.25)	-0.1 (11.67)
		Median	-6.5	0
		Q1, Q3	-20.0, 3.0	-13.0, 13.0
		Min, Max	-33, 13	-14, 20
Week 181	Actual	n	9	8
		Mean (std)	64.4 (26.16)	95.4 (6.93)
		Median	67.0	100.0
		Q1, Q3	67.0, 80.0	90.0, 100.0
		Min, Max	13, 100	83, 100
	Change from BL	n	9	8
		Mean (std)	-16.3 (30.86)	1.1 (9.39)
		Median	-14.0	0
		Q1, Q3	-20.0, -13.0	0, 6.5
		Min, Max	-80, 27	-17, 13

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	58.6 (23.75)	93.5 (9.19)
		Median	60.0	93.5
		Q1, Q3	40.0, 67.0	87.0, 100.0
		Min, Max	33, 93	87, 100
	Change from BL	n	5	2
		Mean (std)	-24.2 (18.95)	-6.5 (9.19)
		Median	-27.0	-6.5
		Q1, Q3	-40.0, -20.0	-13.0, 0
		Min, Max	-40, 6	-13, 0
Week 193	Actual	n	1	0
		Mean (std)	100.0 (-)	
		Median	100.0	
		Q1, Q3	100.0, 100.0	
		Min, Max	100, 100	
	Change from BL	n	1	0
		Mean (std)	13.0 (-)	
		Median	13.0	
		Q1, Q3	13.0, 13.0	
		Min, Max	13, 13	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		100.0 (-)
		Median		100.0
		Q1, Q3		100.0, 100.0
		Min, Max		100, 100
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		100.0 (-)
		Median		100.0
		Q1, Q3		100.0, 100.0
		Min, Max		100, 100
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	50.4 (25.36)	54.6 (26.31)
		Median	47.0	56.5
		Q1, Q3	33.0, 73.0	33.0, 73.0
		Min, Max	0, 100	0, 100
	Change from BL	n	180	176
		Mean (std)	-28.8 (23.42)	-24.6 (23.73)
		Median	-27.0	-20.0
		Q1, Q3	-46.0, -7.0	-40.0, -6.0
		Min, Max	-86, 26	-93, 20
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	88.6 (15.10)	88.6 (15.69)
		Median	93.0	93.0
		Q1, Q3	87.0, 100.0	87.0, 100.0
		Min, Max	7, 100	20, 100
	Change from BL	n	180	176
		Mean (std)	9.6 (16.23)	9.6 (15.13)
		Median	7.0	7.0
		Q1, Q3	0, 14.0	0, 14.0
		Min, Max	-60, 67	-27, 80

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	184	178
		Mean (std)	76.1 (27.42)	79.2 (27.53)
		Median	83.0	91.5
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	178	175
		Mean (std)	74.8 (25.49)	80.7 (24.12)
		Median	75.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	175	173
		Mean (std)	-1.1 (23.57)	1.8 (24.04)
		Median	0	0
		Q1, Q3	-17.0, 16.0	0, 0
		Min, Max	-67, 83	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	165
		Mean (std)	74.8 (27.05)	79.4 (23.10)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	168	163
		Mean (std)	-1.3 (27.73)	0.4 (26.85)
		Median	0	0
		Q1, Q3	-17.0, 16.0	-17.0, 0
		Min, Max	-83, 83	-83, 100
Week 10	Actual	n	168	158
		Mean (std)	73.3 (27.42)	77.2 (25.40)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	163	156
		Mean (std)	-3.7 (31.44)	-2.8 (30.91)
		Median	0	0
		Q1, Q3	-17.0, 16.0	-17.0, 0
		Min, Max	-100, 100	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	159	151
		Mean (std)	72.1 (26.07)	77.7 (25.79)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	154	149
		Mean (std)	-4.6 (33.29)	-3.4 (30.32)
		Median	0	0
		Q1, Q3	-17.0, 0	-16.0, 0
		Min, Max	-100, 100	-100, 100
Week 16	Actual	n	155	151
		Mean (std)	66.0 (29.60)	73.3 (27.83)
		Median	67.0	83.0
		Q1, Q3	41.5, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	150	149
		Mean (std)	-10.5 (36.41)	-8.3 (32.63)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	65.5 (29.23)	74.2 (26.92)
		Median	67.0	79.0
		Q1, Q3	41.5, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	151	150
		Mean (std)	-11.3 (34.86)	-6.6 (32.01)
		Median	-8.5	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 83	-100, 100
Week 25	Actual	n	139	135
		Mean (std)	70.9 (27.51)	78.3 (27.16)
		Median	67.0	83.0
		Q1, Q3	50.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	136	133
		Mean (std)	-6.2 (33.03)	-3.1 (33.68)
		Median	0	0
		Q1, Q3	-33.0, 0	-17.0, 16.0
		Min, Max	-83, 100	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	128	132
		Mean (std)	76.4 (26.07)	80.8 (24.05)
		Median	83.0	87.3
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	124	131
		Mean (std)	-0.6 (32.85)	-1.5 (26.77)
		Median	0	0
		Q1, Q3	-17.0, 17.0	-17.0, 0
		Min, Max	-100, 83	-100, 100
Week 37	Actual	n	116	108
		Mean (std)	78.2 (23.24)	80.0 (22.19)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	113	107
		Mean (std)	-0.4 (30.53)	-2.7 (28.69)
		Median	0	0
		Q1, Q3	-16.0, 0	-17.0, 0
		Min, Max	-100, 100	-100, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	105	107
		Mean (std)	76.7 (23.20)	82.1 (21.15)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	17, 100
	Change from BL	n	103	106
		Mean (std)	-0.8 (28.78)	-2.1 (27.99)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 16.0
		Min, Max	-67, 83	-83, 83
Week 49	Actual	n	94	83
		Mean (std)	76.8 (25.76)	82.9 (23.70)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	92	83
		Mean (std)	-1.8 (27.65)	0.6 (30.06)
		Median	0	0
		Q1, Q3	-16.5, 16.0	-17.0, 17.0
		Min, Max	-83, 67	-100, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	91	84
		Mean (std)	77.3 (25.43)	81.2 (24.48)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	89	83
		Mean (std)	-0.4 (32.76)	-1.3 (31.31)
		Median	0	0
		Q1, Q3	-16.0, 0	-17.0, 17.0
		Min, Max	-100, 100	-100, 83
Week 61	Actual	n	80	65
		Mean (std)	74.6 (27.45)	84.9 (20.51)
		Median	67.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	78	65
		Mean (std)	-2.6 (35.43)	1.8 (26.14)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 17.0
		Min, Max	-100, 100	-100, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	76.5 (24.70)	80.4 (24.84)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	80	72
		Mean (std)	-2.3 (27.66)	-4.8 (29.92)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-67, 83	-100, 67
Week 73	Actual	n	76	62
		Mean (std)	76.6 (22.62)	79.8 (21.97)
		Median	67.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	17, 100
	Change from BL	n	74	62
		Mean (std)	-1.1 (31.71)	-3.2 (30.59)
		Median	0	0
		Q1, Q3	-17.0, 17.0	-17.0, 16.0
		Min, Max	-67, 100	-67, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	76.4 (26.31)	80.5 (26.65)
		Median	83.0	91.5
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	65	57
		Mean (std)	-0.8 (31.11)	-3.8 (33.33)
		Median	0	0
		Q1, Q3	-17.0, 16.0	-17.0, 0
		Min, Max	-83, 83	-83, 83
Week 85	Actual	n	70	58
		Mean (std)	73.4 (25.91)	80.8 (22.21)
		Median	67.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	68	58
		Mean (std)	-2.2 (32.30)	-1.9 (30.34)
		Median	0	0
		Q1, Q3	-17.0, 17.0	-17.0, 0
		Min, Max	-67, 100	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	50
		Mean (std)	73.9 (25.62)	80.3 (25.60)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	17, 100
	Change from BL	n	53	49
		Mean (std)	-3.8 (32.73)	-3.8 (34.30)
		Median	0	0
		Q1, Q3	-33.0, 16.0	-17.0, 0
		Min, Max	-100, 83	-83, 100
Week 97	Actual	n	65	52
		Mean (std)	73.5 (25.57)	79.8 (22.95)
		Median	67.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	63	52
		Mean (std)	-2.2 (29.83)	-3.2 (31.87)
		Median	0	0
		Q1, Q3	-17.0, 17.0	-17.0, 0
		Min, Max	-100, 67	-100, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	76.1 (26.17)	84.1 (19.64)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	54	43
		Mean (std)	1.6 (30.87)	3.9 (27.47)
		Median	0	0
		Q1, Q3	-16.0, 17.0	-16.0, 17.0
		Min, Max	-67, 83	-67, 83
Week 109	Actual	n	52	51
		Mean (std)	77.3 (24.40)	82.7 (21.60)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	51	51
		Mean (std)	2.4 (31.09)	-2.3 (27.91)
		Median	0	0
		Q1, Q3	-16.0, 17.0	-17.0, 0
		Min, Max	-100, 67	-67, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	74.9 (28.16)	79.4 (26.97)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	49	42
		Mean (std)	-0.7 (35.42)	-3.2 (27.86)
		Median	0	0
		Q1, Q3	-33.0, 17.0	-17.0, 0
		Min, Max	-100, 83	-83, 67
Week 121	Actual	n	51	50
		Mean (std)	76.8 (26.90)	76.3 (29.58)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	50.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	50	50
		Mean (std)	-2.0 (29.27)	-7.3 (29.71)
		Median	0	0
		Q1, Q3	-17.0, 0	-33.0, 0
		Min, Max	-83, 83	-67, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	43
		Mean (std)	76.7 (26.20)	81.0 (26.09)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	44	43
		Mean (std)	3.0 (30.45)	-1.1 (32.18)
		Median	0	0
		Q1, Q3	-16.0, 16.0	-17.0, 17.0
		Min, Max	-66, 83	-83, 100
Week 133	Actual	n	48	43
		Mean (std)	75.0 (25.28)	80.3 (27.97)
		Median	67.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	46	43
		Mean (std)	-2.5 (29.14)	-2.3 (31.64)
		Median	0	0
		Q1, Q3	-33.0, 16.0	-17.0, 16.0
		Min, Max	-67, 67	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	75.8 (25.03)	79.4 (26.44)
		Median	75.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	45	36
		Mean (std)	0 (29.57)	-5.8 (32.37)
		Median	0	0
		Q1, Q3	-16.0, 17.0	-17.0, 8.0
		Min, Max	-67, 67	-100, 67
Week 145	Actual	n	38	31
		Mean (std)	75.9 (25.97)	88.7 (19.94)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	33, 100	33, 100
	Change from BL	n	37	31
		Mean (std)	-1.9 (34.41)	0 (21.48)
		Median	0	0
		Q1, Q3	-33.0, 16.0	0, 16.0
		Min, Max	-67, 83	-50, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	72.7 (27.41)	84.8 (23.98)
		Median	67.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	35	24
		Mean (std)	0.5 (31.46)	-3.4 (30.28)
		Median	0	0
		Q1, Q3	-16.0, 16.0	-16.8, 8.5
		Min, Max	-100, 67	-100, 67
Week 157	Actual	n	26	21
		Mean (std)	75.7 (25.10)	85.7 (20.60)
		Median	67.0	100.0
		Q1, Q3	50.0, 100.0	67.0, 100.0
		Min, Max	33, 100	33, 100
	Change from BL	n	26	21
		Mean (std)	-8.3 (36.18)	4.1 (21.68)
		Median	-0.2	0
		Q1, Q3	-33.0, 0	0, 17.0
		Min, Max	-67, 83	-50, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	69.1 (23.81)	93.2 (13.14)
		Median	67.0	100.0
		Q1, Q3	50.0, 100.0	100.0, 100.0
		Min, Max	33, 100	67, 100
	Change from BL	n	21	17
		Mean (std)	-7.1 (30.90)	6.9 (22.84)
		Median	0	0
		Q1, Q3	-33.0, 16.5	0, 17.0
		Min, Max	-67, 50	-33, 67
Week 169	Actual	n	17	11
		Mean (std)	71.6 (29.94)	93.9 (11.22)
		Median	67.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	67, 100
	Change from BL	n	17	11
		Mean (std)	0.1 (37.66)	3.0 (10.12)
		Median	0	0
		Q1, Q3	-33.0, 33.0	0, 16.0
		Min, Max	-50, 83	-17, 17

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	70.9 (31.90)	84.8 (30.22)
		Median	67.0	100.0
		Q1, Q3	58.5, 100.0	83.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	12	11
		Mean (std)	-9.7 (26.06)	1.5 (31.99)
		Median	0	0
		Q1, Q3	-25.0, 0	0, 17.0
		Min, Max	-67, 33	-83, 34
Week 181	Actual	n	9	8
		Mean (std)	63.1 (31.00)	95.9 (11.67)
		Median	67.0	100.0
		Q1, Q3	67.0, 67.0	100.0, 100.0
		Min, Max	0, 100	67, 100
	Change from BL	n	9	8
		Mean (std)	-7.3 (51.46)	0.1 (15.43)
		Median	0	0
		Q1, Q3	-33.0, 17.0	0, 8.5
		Min, Max	-100, 83	-33, 17

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	50.0 (37.34)	91.5 (12.02)
		Median	50.0	91.5
		Q1, Q3	33.0, 67.0	83.0, 100.0
		Min, Max	0, 100	83, 100
	Change from BL	n	5	2
		Mean (std)	-23.4 (30.44)	8.0 (11.31)
		Median	-34.0	8.0
		Q1, Q3	-50.0, 0	0, 16.0
		Min, Max	-50, 17	0, 16
Week 193	Actual	n	1	0
		Mean (std)	100.0 (-)	
		Median	100.0	
		Q1, Q3	100.0, 100.0	
		Min, Max	100, 100	
	Change from BL	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		100.0 (-)
		Median		100.0
		Q1, Q3		100.0, 100.0
		Min, Max		100, 100
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		100.0 (-)
		Median		100.0
		Q1, Q3		100.0, 100.0
		Min, Max		100, 100
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	38.3 (29.78)	46.7 (29.49)
		Median	33.0	50.0
		Q1, Q3	0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	179	176
		Mean (std)	-38.5 (33.34)	-32.7 (34.89)
		Median	-34.0	-33.0
		Q1, Q3	-67.0, -17.0	-50.0, -8.0
		Min, Max	-100, 67	-100, 100
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	90.5 (17.17)	93.0 (16.37)
		Median	100.0	100.0
		Q1, Q3	83.0, 100.0	100.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	179	176
		Mean (std)	14.2 (26.60)	13.7 (24.12)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-33, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	178
		Mean (std)	76.3 (18.59)	79.6 (19.11)
		Median	75.0	83.0
		Q1, Q3	67.0, 92.0	67.0, 92.0
		Min, Max	0, 100	8, 100
Week 4	Actual	n	179	176
		Mean (std)	81.4 (17.74)	82.5 (18.21)
		Median	83.0	83.0
		Q1, Q3	75.0, 100.0	71.0, 100.0
		Min, Max	8, 100	0, 100
	Change from BL	n	177	174
		Mean (std)	4.6 (15.93)	2.9 (16.17)
		Median	0	0
		Q1, Q3	0, 9.0	-8.0, 9.0
		Min, Max	-58, 75	-42, 59

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	167
		Mean (std)	79.8 (19.75)	81.9 (17.64)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	169	165
		Mean (std)	2.8 (16.21)	2.5 (16.40)
		Median	0	0
		Q1, Q3	0, 9.0	-8.0, 9.0
		Min, Max	-92, 75	-34, 67
Week 10	Actual	n	168	158
		Mean (std)	79.5 (19.63)	83.3 (16.26)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	165	156
		Mean (std)	2.8 (17.43)	3.8 (17.95)
		Median	0	0
		Q1, Q3	-8.0, 9.0	-8.0, 9.0
		Min, Max	-92, 75	-34, 75

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	151
		Mean (std)	80.1 (17.83)	80.9 (21.04)
		Median	83.0	83.0
		Q1, Q3	67.0, 96.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	157	149
		Mean (std)	2.7 (18.98)	0.8 (19.86)
		Median	0	0
		Q1, Q3	-8.0, 12.5	-8.0, 9.0
		Min, Max	-92, 75	-75, 59
Week 16	Actual	n	154	150
		Mean (std)	78.4 (20.52)	80.3 (18.47)
		Median	79.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	22, 100	0, 100
	Change from BL	n	151	148
		Mean (std)	1.1 (20.16)	0.9 (20.09)
		Median	0	0
		Q1, Q3	-8.0, 16.0	-8.0, 12.5
		Min, Max	-58, 75	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	77.1 (22.09)	81.7 (17.99)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	8, 100
	Change from BL	n	153	150
		Mean (std)	0.2 (19.40)	2.3 (19.01)
		Median	0	0
		Q1, Q3	-9.0, 9.0	-8.0, 12.5
		Min, Max	-58, 75	-50, 75
Week 25	Actual	n	140	135
		Mean (std)	78.7 (22.23)	80.5 (21.42)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	138	133
		Mean (std)	1.9 (18.61)	1.1 (20.92)
		Median	0	0
		Q1, Q3	-8.0, 9.0	-8.0, 9.0
		Min, Max	-50, 75	-83, 59

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	133
		Mean (std)	79.7 (19.86)	82.7 (18.85)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	127	132
		Mean (std)	3.4 (20.04)	3.0 (20.28)
		Median	0	0
		Q1, Q3	-8.0, 16.0	-8.0, 16.0
		Min, Max	-83, 75	-75, 67
Week 37	Actual	n	115	107
		Mean (std)	83.0 (19.24)	84.6 (16.72)
		Median	92.0	92.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	0, 100	8, 100
	Change from BL	n	113	106
		Mean (std)	4.9 (19.10)	4.5 (21.90)
		Median	8.0	0
		Q1, Q3	0, 17.0	-8.0, 17.0
		Min, Max	-83, 75	-67, 84

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	106	107
		Mean (std)	81.6 (17.36)	83.4 (17.51)
		Median	83.0	92.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	25, 100	0, 100
	Change from BL	n	105	106
		Mean (std)	5.7 (19.08)	3.8 (21.19)
		Median	8.0	0
		Q1, Q3	-8.0, 17.0	0, 17.0
		Min, Max	-50, 75	-75, 84
Week 49	Actual	n	94	83
		Mean (std)	79.6 (22.19)	87.4 (14.96)
		Median	83.0	92.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	92	83
		Mean (std)	2.7 (22.46)	6.7 (19.56)
		Median	0	0
		Q1, Q3	-2.0, 17.0	0, 17.0
		Min, Max	-92, 67	-33, 92

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	92	84
		Mean (std)	81.2 (19.66)	80.1 (19.17)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	25, 100	17, 100
	Change from BL	n	90	83
		Mean (std)	4.6 (20.75)	0.2 (22.63)
		Median	8.0	0
		Q1, Q3	0, 17.0	-16.0, 16.0
		Min, Max	-67, 75	-50, 75
Week 61	Actual	n	80	65
		Mean (std)	80.4 (18.50)	84.6 (17.62)
		Median	83.0	92.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	33, 100	33, 100
	Change from BL	n	78	65
		Mean (std)	3.7 (17.28)	4.0 (21.92)
		Median	0	0
		Q1, Q3	-8.0, 8.0	0, 17.0
		Min, Max	-34, 75	-50, 59

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	78.3 (21.30)	82.5 (16.33)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	25, 100	33, 100
	Change from BL	n	80	72
		Mean (std)	2.7 (19.05)	2.7 (17.45)
		Median	0	0
		Q1, Q3	-8.0, 10.0	-8.0, 8.5
		Min, Max	-42, 75	-42, 59
Week 73	Actual	n	76	62
		Mean (std)	81.3 (19.67)	83.8 (18.03)
		Median	92.0	92.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	33, 100	25, 100
	Change from BL	n	74	62
		Mean (std)	4.1 (20.28)	3.5 (21.00)
		Median	8.0	0
		Q1, Q3	-8.0, 17.0	-8.0, 17.0
		Min, Max	-58, 75	-67, 75

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	79.9 (21.34)	84.4 (18.26)
		Median	83.0	92.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	8, 100	33, 100
	Change from BL	n	65	57
		Mean (std)	4.6 (22.17)	3.5 (18.66)
		Median	8.0	0
		Q1, Q3	0, 17.0	-8.0, 9.0
		Min, Max	-75, 75	-34, 59
Week 85	Actual	n	70	57
		Mean (std)	76.7 (23.22)	83.0 (18.39)
		Median	79.0	83.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	0, 100	17, 100
	Change from BL	n	68	57
		Mean (std)	2.1 (23.55)	5.1 (22.78)
		Median	8.0	0
		Q1, Q3	-8.0, 17.0	0, 17.0
		Min, Max	-75, 50	-83, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	50
		Mean (std)	80.1 (23.00)	83.0 (18.95)
		Median	92.0	87.5
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	53	49
		Mean (std)	4.0 (25.72)	4.9 (20.62)
		Median	8.0	0
		Q1, Q3	0, 17.0	-8.0, 8.0
		Min, Max	-75, 67	-34, 75
Week 97	Actual	n	65	52
		Mean (std)	80.1 (21.39)	84.9 (15.78)
		Median	83.0	92.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	17, 100	33, 100
	Change from BL	n	63	52
		Mean (std)	6.1 (20.95)	5.5 (20.93)
		Median	8.0	0
		Q1, Q3	-8.0, 25.0	-8.0, 17.0
		Min, Max	-42, 75	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	81.3 (19.19)	85.1 (17.80)
		Median	83.0	96.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	33, 100	50, 100
	Change from BL	n	54	43
		Mean (std)	5.6 (20.22)	4.3 (20.01)
		Median	8.0	0
		Q1, Q3	0, 17.0	-8.0, 17.0
		Min, Max	-42, 71	-50, 67
Week 109	Actual	n	52	51
		Mean (std)	82.4 (18.42)	82.1 (16.95)
		Median	87.5	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	17, 100	17, 100
	Change from BL	n	51	51
		Mean (std)	6.2 (19.59)	3.0 (20.96)
		Median	0	0
		Q1, Q3	-8.0, 25.0	-9.0, 9.0
		Min, Max	-34, 75	-50, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	80.7 (21.79)	80.1 (21.80)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	25, 100	0, 100
	Change from BL	n	49	42
		Mean (std)	6.2 (23.46)	2.6 (19.86)
		Median	8.0	0
		Q1, Q3	-6.0, 17.0	-8.0, 17.0
		Min, Max	-75, 75	-50, 59
Week 121	Actual	n	51	50
		Mean (std)	82.2 (21.04)	83.9 (15.71)
		Median	92.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	33, 100	50, 100
	Change from BL	n	50	50
		Mean (std)	5.5 (16.76)	3.7 (18.87)
		Median	4.0	0
		Q1, Q3	0, 17.0	-8.0, 8.0
		Min, Max	-50, 50	-33, 59

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	43
		Mean (std)	81.3 (19.61)	82.1 (19.69)
		Median	92.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	33, 100	33, 100
	Change from BL	n	44	43
		Mean (std)	7.4 (20.82)	2.4 (18.33)
		Median	8.0	0
		Q1, Q3	0, 17.0	-8.0, 17.0
		Min, Max	-42, 67	-34, 67
Week 133	Actual	n	48	43
		Mean (std)	83.8 (15.97)	87.3 (14.39)
		Median	83.0	92.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	42, 100	42, 100
	Change from BL	n	46	43
		Mean (std)	7.6 (20.20)	6.9 (18.53)
		Median	8.0	8.0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-41, 67	-33, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	83.8 (16.59)	81.3 (20.15)
		Median	87.5	87.5
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	42, 100	33, 100
	Change from BL	n	45	36
		Mean (std)	8.8 (20.27)	2.6 (22.24)
		Median	8.0	0
		Q1, Q3	0, 17.0	-12.5, 17.0
		Min, Max	-33, 67	-50, 67
Week 145	Actual	n	38	31
		Mean (std)	84.3 (17.13)	86.2 (17.54)
		Median	92.0	92.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	42, 100	25, 100
	Change from BL	n	37	31
		Mean (std)	6.8 (18.72)	5.1 (17.20)
		Median	8.0	0
		Q1, Q3	0, 17.0	-8.0, 17.0
		Min, Max	-33, 58	-25, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	81.8 (18.54)	86.2 (17.48)
		Median	83.0	92.0
		Q1, Q3	67.0, 100.0	71.0, 100.0
		Min, Max	33, 100	42, 100
	Change from BL	n	35	24
		Mean (std)	8.0 (21.78)	7.0 (12.12)
		Median	8.0	8.0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-59, 67	-16, 25
Week 157	Actual	n	26	21
		Mean (std)	82.4 (18.87)	88.0 (13.58)
		Median	92.0	92.0
		Q1, Q3	67.0, 100.0	79.5, 100.0
		Min, Max	42, 100	67, 100
	Change from BL	n	26	21
		Mean (std)	3.9 (24.62)	10.3 (15.81)
		Median	8.0	9.0
		Q1, Q3	-9.0, 17.0	0, 17.0
		Min, Max	-42, 67	-16, 59

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	78.8 (25.44)	88.4 (13.76)
		Median	83.0	92.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	0, 100	67, 100
	Change from BL	n	21	17
		Mean (std)	7.2 (21.81)	7.5 (18.48)
		Median	8.0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-25, 75	-25, 59
Week 169	Actual	n	17	11
		Mean (std)	85.6 (20.56)	90.2 (16.98)
		Median	92.0	100.0
		Q1, Q3	75.0, 100.0	83.0, 100.0
		Min, Max	25, 100	50, 100
	Change from BL	n	17	11
		Mean (std)	12.8 (21.15)	7.6 (23.56)
		Median	17.0	0
		Q1, Q3	0, 25.0	0, 17.0
		Min, Max	-20, 67	-25, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	86.8 (17.16)	87.9 (15.12)
		Median	100.0	92.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	58, 100	58, 100
	Change from BL	n	12	11
		Mean (std)	11.1 (20.97)	6.1 (19.80)
		Median	4.0	8.0
		Q1, Q3	0, 16.5	-8.0, 17.0
		Min, Max	-16, 58	-17, 50
Week 181	Actual	n	9	8
		Mean (std)	87.0 (18.19)	88.6 (10.85)
		Median	100.0	92.0
		Q1, Q3	83.0, 100.0	83.0, 96.0
		Min, Max	50, 100	67, 100
	Change from BL	n	9	8
		Mean (std)	6.0 (31.96)	9.4 (11.24)
		Median	16.0	12.0
		Q1, Q3	-17.0, 22.0	0, 17.0
		Min, Max	-50, 58	-8, 25

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	60.0 (39.07)	89.0 (15.56)
		Median	67.0	89.0
		Q1, Q3	33.0, 92.0	78.0, 100.0
		Min, Max	8, 100	78, 100
	Change from BL	n	5	2
		Mean (std)	-8.4 (37.29)	1.5 (21.92)
		Median	-17.0	1.5
		Q1, Q3	-25.0, 0	-14.0, 17.0
		Min, Max	-50, 50	-14, 17
Week 193	Actual	n	1	0
		Mean (std)	100.0 (-)	
		Median	100.0	
		Q1, Q3	100.0, 100.0	
		Min, Max	100, 100	
	Change from BL	n	1	0
		Mean (std)	8.0 (-)	
		Median	8.0	
		Q1, Q3	8.0, 8.0	
		Min, Max	8, 8	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		92.0 (-)
		Median		92.0
		Q1, Q3		92.0, 92.0
		Min, Max		92, 92
	Change from BL	n	0	1
		Mean (std)		25.0 (-)
		Median		25.0
		Q1, Q3		25.0, 25.0
		Min, Max		25, 25
Week 205	Actual	n	0	1
		Mean (std)		83.0 (-)
		Median		83.0
		Q1, Q3		83.0, 83.0
		Min, Max		83, 83
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	57.6 (24.50)	61.0 (23.83)
		Median	58.0	67.0
		Q1, Q3	42.0, 75.0	50.0, 75.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	176
		Mean (std)	-19.2 (21.79)	-18.7 (21.80)
		Median	-16.0	-16.0
		Q1, Q3	-33.0, -8.0	-33.0, 0
		Min, Max	-92, 17	-83, 50
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	92.4 (12.62)	93.2 (12.05)
		Median	100.0	100.0
		Q1, Q3	83.0, 100.0	92.0, 100.0
		Min, Max	25, 100	25, 100
	Change from BL	n	181	176
		Mean (std)	15.7 (16.36)	13.4 (18.11)
		Median	16.0	9.0
		Q1, Q3	0, 25.0	0, 21.0
		Min, Max	-58, 75	-42, 92

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	178
		Mean (std)	88.0 (15.63)	89.0 (15.96)
		Median	100.0	100.0
		Q1, Q3	83.0, 100.0	83.0, 100.0
		Min, Max	33, 100	17, 100
Week 4	Actual	n	179	176
		Mean (std)	85.3 (17.39)	87.9 (17.24)
		Median	83.0	100.0
		Q1, Q3	83.0, 100.0	83.0, 100.0
		Min, Max	17, 100	0, 100
	Change from BL	n	177	174
		Mean (std)	-2.9 (16.05)	-1.3 (15.00)
		Median	0	0
		Q1, Q3	-16.0, 0	-16.0, 0
		Min, Max	-67, 34	-50, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	167
		Mean (std)	83.2 (20.39)	86.6 (17.05)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	169	165
		Mean (std)	-5.3 (18.21)	-2.2 (15.52)
		Median	0	0
		Q1, Q3	-17.0, 0	-16.0, 0
		Min, Max	-100, 50	-50, 50
Week 10	Actual	n	169	158
		Mean (std)	83.5 (21.04)	85.5 (17.32)
		Median	83.0	91.5
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	166	156
		Mean (std)	-5.0 (20.84)	-4.1 (16.78)
		Median	0	0
		Q1, Q3	-16.0, 0	-17.0, 0
		Min, Max	-100, 50	-50, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	151
		Mean (std)	83.0 (20.31)	85.0 (19.10)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	157	149
		Mean (std)	-5.4 (20.22)	-5.1 (17.69)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-100, 50	-83, 50
Week 16	Actual	n	155	150
		Mean (std)	80.6 (21.27)	82.1 (19.85)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	17, 100	0, 100
	Change from BL	n	152	148
		Mean (std)	-7.3 (20.20)	-7.5 (18.35)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-83, 67	-67, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	80.6 (23.41)	83.5 (20.18)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	153	150
		Mean (std)	-7.5 (20.70)	-5.6 (18.91)
		Median	0	0
		Q1, Q3	-17.0, 0	-16.0, 0
		Min, Max	-100, 50	-67, 50
Week 25	Actual	n	140	135
		Mean (std)	82.1 (20.88)	82.8 (21.84)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	17, 100	0, 100
	Change from BL	n	138	133
		Mean (std)	-5.7 (16.65)	-6.8 (20.41)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-50, 50	-83, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	133
		Mean (std)	82.7 (21.90)	81.7 (21.37)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	127	132
		Mean (std)	-5.3 (20.75)	-8.1 (19.83)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-100, 67	-67, 50
Week 37	Actual	n	115	107
		Mean (std)	85.2 (21.66)	86.1 (19.05)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	113	106
		Mean (std)	-3.5 (19.83)	-5.0 (16.74)
		Median	0	0
		Q1, Q3	0, 0	-17.0, 0
		Min, Max	-100, 50	-83, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	106	107
		Mean (std)	84.6 (18.93)	86.5 (18.06)
		Median	87.3	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	33, 100	0, 100
	Change from BL	n	105	106
		Mean (std)	-3.4 (15.13)	-4.7 (19.94)
		Median	0	0
		Q1, Q3	0, 0	-17.0, 0
		Min, Max	-67, 34	-83, 50
Week 49	Actual	n	94	83
		Mean (std)	82.2 (21.30)	87.5 (19.25)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	92	83
		Mean (std)	-6.4 (21.43)	-3.3 (20.93)
		Median	0	0
		Q1, Q3	-17.0, 0	-16.0, 0
		Min, Max	-100, 33	-100, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	92	84
		Mean (std)	85.0 (18.19)	85.1 (18.77)
		Median	83.0	100.0
		Q1, Q3	83.0, 100.0	67.0, 100.0
		Min, Max	33, 100	0, 100
	Change from BL	n	90	83
		Mean (std)	-3.7 (16.32)	-6.5 (20.46)
		Median	0	0
		Q1, Q3	-16.0, 0	-17.0, 0
		Min, Max	-67, 33	-100, 50
Week 61	Actual	n	80	65
		Mean (std)	82.2 (22.37)	85.0 (20.52)
		Median	91.5	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	78	65
		Mean (std)	-6.5 (19.28)	-4.1 (22.22)
		Median	0	0
		Q1, Q3	-17.0, 0	-16.0, 0
		Min, Max	-67, 17	-75, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	80.9 (19.74)	87.2 (17.86)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	17, 100	0, 100
	Change from BL	n	80	72
		Mean (std)	-7.3 (19.93)	-4.4 (20.69)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-83, 34	-100, 50
Week 73	Actual	n	76	62
		Mean (std)	83.5 (20.45)	85.2 (18.83)
		Median	83.0	83.0
		Q1, Q3	75.0, 100.0	83.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	74	62
		Mean (std)	-5.4 (18.89)	-3.5 (18.64)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-83, 33	-67, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	83.6 (19.96)	88.0 (17.26)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	17, 100	33, 100
	Change from BL	n	65	57
		Mean (std)	-4.4 (20.05)	-3.1 (19.77)
		Median	0	0
		Q1, Q3	-16.0, 0	-16.0, 0
		Min, Max	-83, 34	-67, 50
Week 85	Actual	n	70	58
		Mean (std)	80.5 (21.77)	84.7 (19.07)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	68	58
		Mean (std)	-7.6 (21.19)	-4.3 (21.99)
		Median	0	0
		Q1, Q3	-17.0, 0	-16.0, 0
		Min, Max	-100, 17	-67, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	50
		Mean (std)	81.2 (22.22)	87.3 (16.99)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	53	49
		Mean (std)	-7.2 (20.80)	-3.0 (20.00)
		Median	0	0
		Q1, Q3	-17.0, 0	-16.0, 0
		Min, Max	-83, 33	-50, 50
Week 97	Actual	n	65	52
		Mean (std)	82.4 (21.20)	86.2 (21.53)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	63	52
		Mean (std)	-4.9 (18.89)	-3.2 (24.26)
		Median	0	0
		Q1, Q3	-17.0, 16.0	-16.5, 8.0
		Min, Max	-50, 34	-100, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	83.2 (19.06)	85.6 (15.45)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	75.0, 100.0
		Min, Max	17, 100	33, 100
	Change from BL	n	54	43
		Mean (std)	-3.5 (15.24)	-4.2 (20.86)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-33, 33	-67, 34
Week 109	Actual	n	52	51
		Mean (std)	82.3 (20.45)	85.3 (16.83)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	33, 100	33, 100
	Change from BL	n	51	51
		Mean (std)	-4.9 (17.47)	-5.8 (19.99)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-67, 17	-67, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	81.4 (20.94)	84.9 (21.10)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	17, 100	17, 100
	Change from BL	n	49	42
		Mean (std)	-7.4 (17.43)	-4.3 (23.30)
		Median	0	0
		Q1, Q3	-17.0, 0	-16.0, 0
		Min, Max	-67, 17	-83, 34
Week 121	Actual	n	51	50
		Mean (std)	83.3 (21.05)	82.0 (15.63)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	17, 100	50, 100
	Change from BL	n	50	50
		Mean (std)	-3.7 (16.65)	-8.3 (18.50)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-50, 34	-50, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	43
		Mean (std)	83.0 (19.91)	85.7 (16.84)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	33, 100	33, 100
	Change from BL	n	44	43
		Mean (std)	-5.6 (18.76)	-4.6 (19.36)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-67, 17	-67, 34
Week 133	Actual	n	48	43
		Mean (std)	83.3 (21.12)	87.7 (15.78)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	17, 100	50, 100
	Change from BL	n	46	43
		Mean (std)	-2.9 (15.76)	-3.3 (19.10)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 17.0
		Min, Max	-34, 33	-50, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	84.8 (17.39)	83.3 (19.47)
		Median	83.0	91.8
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	17, 100	50, 100
	Change from BL	n	45	36
		Mean (std)	-4.4 (15.59)	-5.9 (21.10)
		Median	0	0
		Q1, Q3	-16.0, 0	-17.0, 16.5
		Min, Max	-50, 33	-50, 33
Week 145	Actual	n	38	31
		Mean (std)	82.0 (19.09)	87.9 (14.81)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	33, 100	50, 100
	Change from BL	n	37	31
		Mean (std)	-5.4 (17.67)	-5.0 (18.36)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-50, 34	-50, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	77.8 (23.14)	87.7 (17.68)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	77.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	35	24
		Mean (std)	-7.6 (19.09)	-3.2 (20.10)
		Median	0	0
		Q1, Q3	-17.0, 0	-8.0, 0
		Min, Max	-83, 17	-67, 34
Week 157	Actual	n	26	21
		Mean (std)	82.9 (23.32)	81.0 (17.60)
		Median	85.8	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	50, 100
	Change from BL	n	26	21
		Mean (std)	-8.1 (23.26)	-10.1 (23.29)
		Median	0	0
		Q1, Q3	-16.0, 0	-33.0, 0
		Min, Max	-100, 17	-50, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	81.3 (23.32)	86.3 (19.73)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	33, 100	33, 100
	Change from BL	n	21	17
		Mean (std)	-3.6 (16.45)	-5.8 (18.58)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-34, 33	-33, 17
Week 169	Actual	n	17	11
		Mean (std)	78.4 (22.67)	84.9 (15.58)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	33, 100	67, 100
	Change from BL	n	17	11
		Mean (std)	-4.9 (14.24)	-7.5 (20.25)
		Median	0	0
		Q1, Q3	-17.0, 0	-33.0, 0
		Min, Max	-34, 17	-33, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	80.4 (21.15)	89.4 (13.42)
		Median	83.0	100.0
		Q1, Q3	75.0, 100.0	83.0, 100.0
		Min, Max	33, 100	67, 100
	Change from BL	n	12	11
		Mean (std)	-9.8 (16.68)	-9.1 (11.41)
		Median	-8.0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-50, 17	-33, 0
Week 181	Actual	n	9	8
		Mean (std)	70.4 (25.91)	91.5 (9.09)
		Median	67.0	91.5
		Q1, Q3	67.0, 83.0	83.0, 100.0
		Min, Max	17, 100	83, 100
	Change from BL	n	9	8
		Mean (std)	-14.7 (28.13)	-8.5 (9.09)
		Median	-16.0	-8.5
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-83, 17	-17, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	60.2 (30.19)	91.5 (12.02)
		Median	67.0	91.5
		Q1, Q3	50.0, 67.0	83.0, 100.0
		Min, Max	17, 100	83, 100
	Change from BL	n	5	2
		Mean (std)	-19.8 (13.81)	-8.5 (12.02)
		Median	-17.0	-8.5
		Q1, Q3	-33.0, -16.0	-17.0, 0
		Min, Max	-33, 0	-17, 0
Week 193	Actual	n	1	0
		Mean (std)	100.0 (-)	
		Median	100.0	
		Q1, Q3	100.0, 100.0	
		Min, Max	100, 100	
	Change from BL	n	1	0
		Mean (std)	17.0 (-)	
		Median	17.0	
		Q1, Q3	17.0, 17.0	
		Min, Max	17, 17	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		100.0 (-)
		Median		100.0
		Q1, Q3		100.0, 100.0
		Min, Max		100, 100
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		100.0 (-)
		Median		100.0
		Q1, Q3		100.0, 100.0
		Min, Max		100, 100
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	60.7 (26.62)	64.3 (23.93)
		Median	67.0	67.0
		Q1, Q3	50.0, 83.0	50.0, 83.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	176
		Mean (std)	-27.3 (24.92)	-24.8 (21.60)
		Median	-17.0	-17.0
		Q1, Q3	-33.0, -16.0	-33.0, -16.0
		Min, Max	-100, 33	-100, 34
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	94.7 (11.77)	95.9 (10.42)
		Median	100.0	100.0
		Q1, Q3	100.0, 100.0	100.0, 100.0
		Min, Max	17, 100	33, 100
	Change from BL	n	181	176
		Mean (std)	6.6 (15.84)	6.7 (13.73)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-83, 67	-34, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	177
		Mean (std)	81.0 (22.87)	84.0 (22.39)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	179	176
		Mean (std)	78.0 (24.00)	81.8 (22.81)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	177	173
		Mean (std)	-2.9 (22.73)	-2.1 (22.09)
		Median	0	0
		Q1, Q3	-16.0, 0	-16.0, 0
		Min, Max	-83, 67	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	167
		Mean (std)	78.4 (23.67)	82.0 (21.48)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	169	164
		Mean (std)	-2.5 (27.58)	-1.4 (23.37)
		Median	0	0
		Q1, Q3	-17.0, 0	-16.0, 0
		Min, Max	-67, 100	-67, 100
Week 10	Actual	n	168	158
		Mean (std)	79.0 (25.40)	81.5 (20.93)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	165	155
		Mean (std)	-2.7 (28.97)	-2.6 (24.83)
		Median	0	0
		Q1, Q3	-17.0, 16.0	-17.0, 0
		Min, Max	-100, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	151
		Mean (std)	78.1 (23.65)	79.4 (24.75)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	157	148
		Mean (std)	-3.3 (28.02)	-5.4 (29.54)
		Median	0	0
		Q1, Q3	-17.0, 16.0	-17.0, 0
		Min, Max	-100, 100	-100, 100
Week 16	Actual	n	155	150
		Mean (std)	76.8 (23.40)	79.4 (24.14)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	147
		Mean (std)	-4.6 (27.99)	-5.4 (26.37)
		Median	0	0
		Q1, Q3	-17.0, 16.0	-17.0, 0
		Min, Max	-100, 100	-100, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	76.5 (23.96)	80.6 (23.30)
		Median	83.0	83.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	153	149
		Mean (std)	-5.0 (30.02)	-3.9 (25.67)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-100, 100	-100, 100
Week 25	Actual	n	140	135
		Mean (std)	78.7 (23.90)	83.7 (23.48)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	138	132
		Mean (std)	-3.0 (27.25)	-1.2 (27.07)
		Median	0	0
		Q1, Q3	-17.0, 0	-16.0, 16.8
		Min, Max	-67, 100	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	133
		Mean (std)	79.4 (24.45)	83.3 (24.00)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	127	131
		Mean (std)	-2.7 (29.60)	-2.9 (27.02)
		Median	0	0
		Q1, Q3	-16.0, 0	-16.5, 8.5
		Min, Max	-100, 100	-100, 100
Week 37	Actual	n	115	107
		Mean (std)	84.2 (22.01)	85.8 (21.78)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	113	105
		Mean (std)	2.2 (27.19)	-0.9 (26.49)
		Median	0	0
		Q1, Q3	0, 16.0	-0.5, 17.0
		Min, Max	-100, 100	-100, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	106	107
		Mean (std)	82.1 (23.52)	85.9 (22.70)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	17, 100	0, 100
	Change from BL	n	105	105
		Mean (std)	-0.1 (26.30)	-0.5 (27.11)
		Median	0	0
		Q1, Q3	-16.0, 0	0, 17.0
		Min, Max	-67, 100	-83, 83
Week 49	Actual	n	94	83
		Mean (std)	81.4 (25.49)	88.8 (17.99)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	17, 100
	Change from BL	n	92	82
		Mean (std)	0.2 (29.00)	1.5 (24.24)
		Median	0	0
		Q1, Q3	-8.0, 16.0	0, 17.0
		Min, Max	-100, 100	-67, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	91	84
		Mean (std)	83.6 (21.82)	83.1 (24.68)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	89	82
		Mean (std)	1.4 (25.72)	-2.3 (29.34)
		Median	0	0
		Q1, Q3	0, 17.0	-16.0, 17.0
		Min, Max	-67, 100	-100, 100
Week 61	Actual	n	80	65
		Mean (std)	80.4 (26.85)	87.7 (20.03)
		Median	91.5	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	78	64
		Mean (std)	-0.8 (29.68)	1.4 (27.42)
		Median	0	0
		Q1, Q3	-16.0, 0	0, 17.0
		Min, Max	-100, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	82.4 (23.00)	86.5 (20.51)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	80	71
		Mean (std)	0.7 (27.49)	-1.1 (27.47)
		Median	0	0
		Q1, Q3	-16.0, 17.0	-16.0, 17.0
		Min, Max	-67, 100	-100, 83
Week 73	Actual	n	76	62
		Mean (std)	84.9 (19.43)	89.2 (18.12)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	33, 100	33, 100
	Change from BL	n	74	61
		Mean (std)	1.6 (26.24)	3.1 (26.78)
		Median	0	0
		Q1, Q3	-16.0, 17.0	0, 17.0
		Min, Max	-50, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	81.1 (27.52)	86.5 (23.21)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	65	56
		Mean (std)	1.3 (30.26)	-1.4 (27.58)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-100, 83	-100, 50
Week 85	Actual	n	70	57
		Mean (std)	80.7 (25.74)	87.4 (17.32)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	68	57
		Mean (std)	-0.7 (30.16)	0.3 (24.42)
		Median	0	0
		Q1, Q3	-17.0, 17.0	-16.0, 17.0
		Min, Max	-83, 100	-67, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	50
		Mean (std)	82.8 (22.41)	86.9 (19.90)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	53	49
		Mean (std)	0.7 (34.75)	0.6 (26.27)
		Median	0	0
		Q1, Q3	-33.0, 17.0	0, 17.0
		Min, Max	-83, 100	-67, 83
Week 97	Actual	n	65	52
		Mean (std)	82.1 (24.46)	89.8 (18.04)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	17, 100
	Change from BL	n	63	52
		Mean (std)	2.4 (30.49)	1.0 (26.20)
		Median	0	0
		Q1, Q3	-16.0, 17.0	0, 17.0
		Min, Max	-83, 67	-83, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	78.5 (26.16)	89.0 (19.36)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	54	43
		Mean (std)	-0.6 (29.19)	3.9 (20.20)
		Median	0	0
		Q1, Q3	-17.0, 17.0	0, 17.0
		Min, Max	-67, 67	-67, 50
Week 109	Actual	n	52	51
		Mean (std)	79.2 (27.37)	87.6 (19.35)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	51	51
		Mean (std)	0.1 (35.01)	-1.9 (24.14)
		Median	0	0
		Q1, Q3	-16.0, 17.0	-16.0, 0
		Min, Max	-100, 100	-67, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	83.0 (24.81)	84.5 (22.28)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	49	42
		Mean (std)	2.0 (31.32)	-1.2 (25.12)
		Median	0	0
		Q1, Q3	-17.0, 17.0	0, 17.0
		Min, Max	-67, 100	-67, 50
Week 121	Actual	n	51	50
		Mean (std)	82.4 (19.51)	87.3 (18.60)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	33, 100	33, 100
	Change from BL	n	50	50
		Mean (std)	1.1 (21.40)	1.4 (22.57)
		Median	0	0
		Q1, Q3	-16.0, 17.0	0, 17.0
		Min, Max	-50, 50	-67, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	43
		Mean (std)	82.2 (27.82)	88.0 (22.82)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	44	43
		Mean (std)	4.2 (27.00)	-1.5 (29.29)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-67, 67	-100, 83
Week 133	Actual	n	48	43
		Mean (std)	79.9 (24.74)	86.1 (19.52)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	46	43
		Mean (std)	0.4 (27.61)	-1.9 (22.74)
		Median	0	0
		Q1, Q3	-16.0, 0	0, 17.0
		Min, Max	-67, 67	-67, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	80.1 (27.33)	82.4 (27.30)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	45	36
		Mean (std)	1.8 (33.04)	-5.5 (29.60)
		Median	0	0
		Q1, Q3	-16.0, 17.0	-8.5, 17.0
		Min, Max	-100, 67	-67, 50
Week 145	Actual	n	38	31
		Mean (std)	83.8 (20.96)	94.9 (10.64)
		Median	91.5	100.0
		Q1, Q3	67.0, 100.0	100.0, 100.0
		Min, Max	0, 100	67, 100
	Change from BL	n	37	31
		Mean (std)	3.2 (27.43)	3.5 (15.44)
		Median	0	0
		Q1, Q3	-16.0, 17.0	0, 0
		Min, Max	-67, 67	-33, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	80.6 (28.30)	89.5 (16.91)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	35	24
		Mean (std)	3.8 (35.08)	0.7 (17.38)
		Median	0	0
		Q1, Q3	0, 33.0	0, 16.5
		Min, Max	-100, 67	-50, 33
Week 157	Actual	n	26	21
		Mean (std)	80.8 (25.65)	85.7 (21.94)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	26	21
		Mean (std)	-4.4 (29.29)	-0.7 (20.79)
		Median	0	0
		Q1, Q3	-33.0, 17.0	0, 17.0
		Min, Max	-67, 67	-50, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	73.9 (23.84)	95.1 (14.11)
		Median	67.0	100.0
		Q1, Q3	67.0, 100.0	100.0, 100.0
		Min, Max	17, 100	50, 100
	Change from BL	n	21	17
		Mean (std)	-7.0 (30.92)	6.9 (20.49)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 17.0
		Min, Max	-66, 67	-50, 50
Week 169	Actual	n	17	11
		Mean (std)	72.6 (32.75)	90.9 (17.23)
		Median	83.0	100.0
		Q1, Q3	67.0, 100.0	83.0, 100.0
		Min, Max	0, 100	50, 100
	Change from BL	n	17	11
		Mean (std)	-5.9 (35.46)	0.1 (19.86)
		Median	0	0
		Q1, Q3	-17.0, 0	0, 17.0
		Min, Max	-67, 67	-50, 17

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	73.8 (27.89)	94.0 (13.35)
		Median	67.0	100.0
		Q1, Q3	67.0, 100.0	100.0, 100.0
		Min, Max	0, 100	67, 100
	Change from BL	n	12	11
		Mean (std)	-13.8 (18.47)	4.7 (10.80)
		Median	-8.5	0
		Q1, Q3	-33.0, 0	0, 17.0
		Min, Max	-33, 17	-16, 17
Week 181	Actual	n	9	8
		Mean (std)	74.1 (26.54)	100.0 (0)
		Median	67.0	100.0
		Q1, Q3	50.0, 100.0	100.0, 100.0
		Min, Max	33, 100	100, 100
	Change from BL	n	9	8
		Mean (std)	-7.3 (35.58)	4.3 (7.87)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 8.5
		Min, Max	-50, 67	0, 17

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	60.0 (43.53)	100.0 (0)
		Median	67.0	100.0
		Q1, Q3	33.0, 100.0	100.0, 100.0
		Min, Max	0, 100	100, 100
	Change from BL	n	5	2
		Mean (std)	-16.8 (44.22)	0 (0)
		Median	-33.0	0
		Q1, Q3	-34.0, 0	0, 0
		Min, Max	-67, 50	0, 0
Week 193	Actual	n	1	0
		Mean (std)	100.0 (-)	
		Median	100.0	
		Q1, Q3	100.0, 100.0	
		Min, Max	100, 100	
	Change from BL	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		100.0 (-)
		Median		100.0
		Q1, Q3		100.0, 100.0
		Min, Max		100, 100
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		100.0 (-)
		Median		100.0
		Q1, Q3		100.0, 100.0
		Min, Max		100, 100
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	48.6 (28.00)	54.7 (28.11)
		Median	50.0	50.0
		Q1, Q3	33.0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	175
		Mean (std)	-32.3 (30.38)	-29.2 (29.93)
		Median	-33.0	-33.0
		Q1, Q3	-50.0, -16.0	-50.0, 0
		Min, Max	-100, 34	-100, 50
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	93.5 (15.53)	95.2 (12.75)
		Median	100.0	100.0
		Q1, Q3	100.0, 100.0	100.0, 100.0
		Min, Max	0, 100	17, 100
	Change from BL	n	181	175
		Mean (std)	12.5 (25.25)	11.3 (21.38)
		Median	0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	-100, 100	-50, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	178
		Mean (std)	29.9 (21.26)	28.5 (22.17)
		Median	33.0	22.0
		Q1, Q3	11.0, 44.0	11.0, 33.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	179	176
		Mean (std)	34.7 (22.32)	31.2 (19.91)
		Median	33.0	33.0
		Q1, Q3	22.0, 44.0	22.0, 44.0
		Min, Max	0, 100	0, 100
	Change from BL	n	177	174
		Mean (std)	4.8 (19.73)	3.0 (19.02)
		Median	0	0
		Q1, Q3	-11.0, 12.0	-11.0, 11.0
		Min, Max	-45, 67	-56, 56

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	165
		Mean (std)	35.8 (22.44)	31.3 (21.66)
		Median	33.0	33.0
		Q1, Q3	22.0, 44.0	22.0, 44.0
		Min, Max	0, 100	0, 100
	Change from BL	n	169	163
		Mean (std)	6.0 (21.03)	3.7 (21.74)
		Median	0	0
		Q1, Q3	0, 22.0	-11.0, 12.0
		Min, Max	-67, 67	-67, 67
Week 10	Actual	n	169	157
		Mean (std)	38.9 (24.06)	33.0 (23.93)
		Median	33.0	33.0
		Q1, Q3	22.0, 56.0	22.0, 44.0
		Min, Max	0, 100	0, 100
	Change from BL	n	166	155
		Mean (std)	9.4 (24.01)	5.9 (25.68)
		Median	11.0	0
		Q1, Q3	0, 22.0	-11.0, 22.0
		Min, Max	-89, 67	-56, 89

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	151
		Mean (std)	38.7 (23.44)	35.0 (23.50)
		Median	33.0	33.0
		Q1, Q3	22.0, 44.0	22.0, 56.0
		Min, Max	0, 100	0, 100
	Change from BL	n	157	149
		Mean (std)	10.0 (26.01)	7.8 (24.98)
		Median	11.0	11.0
		Q1, Q3	0, 22.0	0, 22.0
		Min, Max	-67, 78	-67, 89
Week 16	Actual	n	155	151
		Mean (std)	42.6 (27.92)	36.5 (26.11)
		Median	33.0	33.0
		Q1, Q3	22.0, 67.0	22.0, 56.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	149
		Mean (std)	12.7 (28.61)	10.1 (24.90)
		Median	11.0	11.0
		Q1, Q3	-5.5, 33.0	0, 23.0
		Min, Max	-67, 89	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	151
		Mean (std)	41.0 (26.10)	35.2 (24.37)
		Median	33.0	33.0
		Q1, Q3	22.0, 56.0	22.0, 44.0
		Min, Max	0, 100	0, 100
	Change from BL	n	153	149
		Mean (std)	11.6 (27.21)	8.7 (26.47)
		Median	11.0	11.0
		Q1, Q3	-11.0, 33.0	0, 22.0
		Min, Max	-67, 89	-56, 100
Week 25	Actual	n	140	135
		Mean (std)	34.0 (24.45)	26.7 (23.01)
		Median	33.0	22.0
		Q1, Q3	22.0, 44.0	11.0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	138	133
		Mean (std)	4.4 (24.68)	0.6 (23.76)
		Median	0	0
		Q1, Q3	-11.0, 22.0	-11.0, 11.0
		Min, Max	-67, 67	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	128	132
		Mean (std)	31.7 (24.93)	27.3 (20.74)
		Median	33.0	22.0
		Q1, Q3	11.0, 44.0	11.0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	126	131
		Mean (std)	1.9 (26.16)	2.0 (20.44)
		Median	0	0
		Q1, Q3	-11.0, 11.0	-11.0, 11.0
		Min, Max	-78, 89	-56, 67
Week 37	Actual	n	116	107
		Mean (std)	25.2 (21.84)	25.8 (21.49)
		Median	22.0	22.0
		Q1, Q3	11.0, 33.0	11.0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	114	106
		Mean (std)	-2.3 (25.02)	1.3 (23.46)
		Median	0	0
		Q1, Q3	-12.0, 11.0	-11.0, 11.0
		Min, Max	-89, 100	-67, 78

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	105	107
		Mean (std)	28.9 (21.68)	24.2 (19.90)
		Median	22.0	22.0
		Q1, Q3	22.0, 33.0	11.0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	104	106
		Mean (std)	-0.4 (21.36)	0.1 (21.00)
		Median	0	0
		Q1, Q3	-11.0, 11.0	-11.0, 11.0
		Min, Max	-67, 67	-67, 56
Week 49	Actual	n	94	83
		Mean (std)	29.1 (21.20)	24.2 (17.35)
		Median	22.0	22.0
		Q1, Q3	11.0, 33.0	11.0, 33.0
		Min, Max	0, 100	0, 78
	Change from BL	n	92	83
		Mean (std)	0.1 (21.69)	-0.9 (21.07)
		Median	0	0
		Q1, Q3	-11.0, 11.0	-11.0, 11.0
		Min, Max	-67, 67	-67, 45

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	91	84
		Mean (std)	29.4 (22.49)	28.4 (21.28)
		Median	33.0	27.5
		Q1, Q3	11.0, 33.0	11.0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	89	83
		Mean (std)	0.7 (22.65)	4.1 (21.92)
		Median	0	0
		Q1, Q3	-11.0, 11.0	-11.0, 11.0
		Min, Max	-78, 67	-56, 78
Week 61	Actual	n	80	65
		Mean (std)	27.1 (22.23)	24.5 (20.30)
		Median	22.0	22.0
		Q1, Q3	11.0, 33.0	11.0, 33.0
		Min, Max	0, 100	0, 89
	Change from BL	n	78	65
		Mean (std)	-1.1 (23.78)	-0.1 (22.32)
		Median	0	0
		Q1, Q3	-11.0, 11.0	-11.0, 11.0
		Min, Max	-67, 56	-78, 56

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	81	73
		Mean (std)	31.7 (24.00)	26.9 (20.99)
		Median	33.0	22.0
		Q1, Q3	11.0, 44.0	11.0, 33.0
		Min, Max	0, 89	0, 100
	Change from BL	n	79	72
		Mean (std)	2.6 (24.20)	3.1 (21.18)
		Median	0	0
		Q1, Q3	-11.0, 11.0	-11.0, 11.0
		Min, Max	-78, 67	-56, 56
Week 73	Actual	n	75	62
		Mean (std)	29.0 (20.55)	29.0 (20.61)
		Median	33.0	22.0
		Q1, Q3	22.0, 33.0	22.0, 33.0
		Min, Max	0, 89	0, 100
	Change from BL	n	73	62
		Mean (std)	1.7 (24.17)	5.6 (23.64)
		Median	0	0
		Q1, Q3	-11.0, 11.0	-11.0, 22.0
		Min, Max	-67, 67	-56, 78

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	66	58
		Mean (std)	27.7 (22.40)	27.6 (24.61)
		Median	22.0	22.0
		Q1, Q3	11.0, 33.0	11.0, 33.0
		Min, Max	0, 89	0, 100
	Change from BL	n	64	57
		Mean (std)	-1.1 (22.63)	3.9 (24.87)
		Median	0	0
		Q1, Q3	-11.0, 11.0	0, 11.0
		Min, Max	-78, 67	-78, 67
Week 85	Actual	n	70	58
		Mean (std)	30.1 (24.64)	25.9 (20.81)
		Median	22.0	22.0
		Q1, Q3	11.0, 44.0	11.0, 33.0
		Min, Max	0, 100	0, 89
	Change from BL	n	68	58
		Mean (std)	-0.9 (24.43)	1.4 (22.39)
		Median	0	0
		Q1, Q3	-11.0, 11.0	-11.0, 11.0
		Min, Max	-56, 78	-78, 45

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	50
		Mean (std)	28.7 (23.16)	26.5 (23.93)
		Median	22.0	22.0
		Q1, Q3	22.0, 33.0	11.0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	53	49
		Mean (std)	0.1 (23.12)	4.1 (27.87)
		Median	0	0
		Q1, Q3	-11.0, 11.0	-11.0, 22.0
		Min, Max	-67, 56	-67, 67
Week 97	Actual	n	65	52
		Mean (std)	32.4 (25.39)	25.5 (19.45)
		Median	33.0	22.0
		Q1, Q3	22.0, 44.0	11.0, 33.0
		Min, Max	0, 100	0, 89
	Change from BL	n	63	52
		Mean (std)	1.6 (26.38)	1.8 (22.80)
		Median	0	0
		Q1, Q3	-11.0, 11.0	0, 11.0
		Min, Max	-67, 78	-78, 56

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	29.3 (26.34)	23.3 (19.00)
		Median	22.0	22.0
		Q1, Q3	11.0, 33.0	11.0, 33.0
		Min, Max	0, 100	0, 89
	Change from BL	n	54	43
		Mean (std)	-2.3 (24.68)	-0.3 (20.37)
		Median	0	0
		Q1, Q3	-11.0, 0	-11.0, 11.0
		Min, Max	-67, 67	-56, 56
Week 109	Actual	n	52	51
		Mean (std)	30.6 (24.11)	23.9 (23.20)
		Median	33.0	22.0
		Q1, Q3	11.0, 33.0	0, 33.0
		Min, Max	0, 100	0, 89
	Change from BL	n	51	51
		Mean (std)	2.5 (29.68)	2.0 (22.70)
		Median	0	0
		Q1, Q3	-11.0, 22.0	-11.0, 11.0
		Min, Max	-67, 89	-67, 56

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	29.7 (26.94)	28.1 (23.64)
		Median	33.0	22.0
		Q1, Q3	11.0, 33.0	11.0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	49	42
		Mean (std)	-1.4 (23.81)	5.1 (23.34)
		Median	0	0
		Q1, Q3	-22.0, 22.0	-11.0, 22.0
		Min, Max	-67, 56	-56, 67
Week 121	Actual	n	51	50
		Mean (std)	30.4 (25.01)	30.8 (23.56)
		Median	22.0	22.0
		Q1, Q3	11.0, 44.0	17.0, 44.0
		Min, Max	0, 100	0, 100
	Change from BL	n	50	50
		Mean (std)	2.6 (24.08)	8.6 (27.35)
		Median	0	11.0
		Q1, Q3	-11.0, 11.0	-5.0, 23.0
		Min, Max	-56, 56	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	42
		Mean (std)	25.6 (20.13)	27.1 (25.46)
		Median	22.0	22.0
		Q1, Q3	11.0, 33.0	11.0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	44	42
		Mean (std)	-5.1 (22.47)	3.0 (26.43)
		Median	0	0
		Q1, Q3	-22.0, 5.5	-11.0, 22.0
		Min, Max	-67, 34	-67, 78
Week 133	Actual	n	48	43
		Mean (std)	28.4 (24.42)	28.9 (23.75)
		Median	22.0	22.0
		Q1, Q3	11.0, 44.0	11.0, 44.0
		Min, Max	0, 100	0, 100
	Change from BL	n	46	43
		Mean (std)	-1.1 (22.45)	4.5 (25.53)
		Median	0	0
		Q1, Q3	-11.0, 11.0	-11.0, 11.0
		Min, Max	-67, 45	-67, 78

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	30.3 (24.38)	30.1 (26.17)
		Median	33.0	22.0
		Q1, Q3	11.0, 33.0	11.0, 38.5
		Min, Max	0, 89	0, 100
	Change from BL	n	45	36
		Mean (std)	1.4 (27.48)	7.2 (26.94)
		Median	0	0
		Q1, Q3	-11.0, 22.0	-5.5, 11.0
		Min, Max	-67, 56	-67, 67
Week 145	Actual	n	38	31
		Mean (std)	30.9 (25.79)	19.0 (19.50)
		Median	33.0	11.0
		Q1, Q3	11.0, 33.0	11.0, 22.0
		Min, Max	0, 100	0, 100
	Change from BL	n	37	31
		Mean (std)	4.4 (26.87)	0.9 (22.67)
		Median	0	0
		Q1, Q3	-11.0, 22.0	0, 11.0
		Min, Max	-56, 78	-78, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	33.2 (27.26)	22.7 (17.13)
		Median	33.0	22.0
		Q1, Q3	11.0, 44.0	11.0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	35	24
		Mean (std)	-0.5 (24.56)	2.9 (22.51)
		Median	0	0
		Q1, Q3	-11.0, 11.0	-4.1, 11.0
		Min, Max	-56, 56	-67, 45
Week 157	Actual	n	26	21
		Mean (std)	33.6 (22.45)	24.7 (17.92)
		Median	33.0	22.0
		Q1, Q3	22.0, 44.0	11.0, 33.0
		Min, Max	0, 89	0, 67
	Change from BL	n	26	21
		Mean (std)	8.8 (28.14)	-0.5 (18.01)
		Median	11.0	0
		Q1, Q3	0, 22.7	-11.0, 11.0
		Min, Max	-67, 67	-56, 22

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	36.3 (21.81)	20.1 (15.18)
		Median	33.0	11.0
		Q1, Q3	22.0, 44.0	11.0, 33.0
		Min, Max	0, 89	0, 44
	Change from BL	n	21	17
		Mean (std)	2.8 (25.29)	-1.4 (29.24)
		Median	0	0
		Q1, Q3	-11.0, 11.0	0, 11.0
		Min, Max	-44, 67	-78, 44
Week 169	Actual	n	17	11
		Mean (std)	41.1 (29.72)	15.5 (12.26)
		Median	33.0	11.0
		Q1, Q3	22.0, 56.0	11.0, 22.0
		Min, Max	0, 100	0, 44
	Change from BL	n	17	11
		Mean (std)	7.9 (28.22)	-2.5 (15.42)
		Median	0	0
		Q1, Q3	0, 22.0	-11.0, 11.0
		Min, Max	-44, 67	-33, 22

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	40.7 (32.68)	13.0 (9.61)
		Median	38.5	11.0
		Q1, Q3	11.0, 67.0	11.0, 22.0
		Min, Max	0, 100	0, 33
	Change from BL	n	12	11
		Mean (std)	13.9 (24.74)	-4.0 (16.52)
		Median	11.0	0
		Q1, Q3	-5.5, 27.5	-11.0, 0
		Min, Max	-22, 56	-44, 22
Week 181	Actual	n	9	8
		Mean (std)	50.7 (29.60)	15.1 (10.08)
		Median	56.0	11.0
		Q1, Q3	33.0, 67.0	11.0, 22.0
		Min, Max	0, 89	0, 33
	Change from BL	n	9	8
		Mean (std)	21.2 (32.73)	4.1 (5.69)
		Median	22.0	0
		Q1, Q3	0, 45.0	0, 11.0
		Min, Max	-33, 67	0, 11

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	53.6 (30.96)	11.0 (15.56)
		Median	67.0	11.0
		Q1, Q3	56.0, 67.0	0, 22.0
		Min, Max	0, 78	0, 22
	Change from BL	n	5	2
		Mean (std)	20.4 (26.75)	5.5 (7.78)
		Median	23.0	5.5
		Q1, Q3	0, 34.0	0, 11.0
		Min, Max	-11, 56	0, 11
Week 193	Actual	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	-11.0 (-)	
		Median	-11.0	
		Q1, Q3	-11.0, -11.0	
		Min, Max	-11, -11	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		22.0 (-)
		Median		22.0
		Q1, Q3		22.0, 22.0
		Min, Max		22, 22
	Change from BL	n	0	1
		Mean (std)		11.0 (-)
		Median		11.0
		Q1, Q3		11.0, 11.0
		Min, Max		11, 11
Week 205	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	16.1 (17.45)	14.6 (18.28)
		Median	11.0	11.0
		Q1, Q3	0, 22.0	0, 22.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	176
		Mean (std)	-13.5 (21.02)	-13.7 (19.67)
		Median	-11.0	-11.0
		Q1, Q3	-22.0, 0	-22.0, 0
		Min, Max	-89, 67	-78, 56
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	64.1 (25.54)	58.8 (24.90)
		Median	67.0	56.0
		Q1, Q3	44.0, 89.0	44.0, 78.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	176
		Mean (std)	34.5 (24.20)	30.7 (25.47)
		Median	33.0	33.0
		Q1, Q3	16.0, 56.0	11.0, 45.0
		Min, Max	-23, 100	-34, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	178
		Mean (std)	6.8 (12.69)	8.1 (17.10)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 67	0, 100
Week 4	Actual	n	179	176
		Mean (std)	10.0 (16.69)	9.6 (16.59)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	177	174
		Mean (std)	3.3 (14.98)	1.9 (19.21)
		Median	0	0
		Q1, Q3	0, 16.0	0, 0
		Min, Max	-50, 67	-83, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	171	166
		Mean (std)	9.4 (15.26)	6.8 (12.32)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 83	0, 50
	Change from BL	n	168	164
		Mean (std)	2.8 (15.46)	-0.7 (15.15)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 83	-50, 50
Week 10	Actual	n	169	157
		Mean (std)	9.1 (16.46)	6.3 (12.46)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 100	0, 67
	Change from BL	n	166	155
		Mean (std)	2.3 (18.15)	-0.5 (16.94)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 100	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	151
		Mean (std)	7.4 (11.39)	8.4 (15.82)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 59	0, 100
	Change from BL	n	157	149
		Mean (std)	1.2 (16.41)	1.6 (16.93)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 59	-66, 100
Week 16	Actual	n	155	151
		Mean (std)	9.1 (15.23)	8.6 (17.41)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 67	0, 100
	Change from BL	n	152	149
		Mean (std)	2.4 (17.74)	1.4 (16.39)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-66, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	151
		Mean (std)	7.9 (13.02)	5.4 (11.17)
		Median	0	0
		Q1, Q3	0, 17.0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	153	149
		Mean (std)	1.6 (16.30)	-2.0 (16.04)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 67	-83, 42
Week 25	Actual	n	140	135
		Mean (std)	5.3 (14.60)	5.7 (15.52)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	138	133
		Mean (std)	-0.9 (16.00)	-1.9 (18.40)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 83	-83, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	131
		Mean (std)	5.7 (13.90)	5.7 (16.93)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	127	130
		Mean (std)	0 (15.17)	-1.8 (16.30)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 67	-66, 100
Week 37	Actual	n	116	107
		Mean (std)	5.1 (13.05)	6.5 (17.57)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	114	106
		Mean (std)	-0.3 (14.88)	0.7 (16.49)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 83	-33, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	105	107
		Mean (std)	4.6 (11.01)	5.2 (14.38)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	104	106
		Mean (std)	-0.8 (13.86)	-0.6 (16.89)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 50	-66, 100
Week 49	Actual	n	94	83
		Mean (std)	6.2 (16.91)	3.4 (10.05)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	92	83
		Mean (std)	1.3 (19.06)	-2.2 (12.70)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 100	-33, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	91	84
		Mean (std)	4.4 (12.45)	5.6 (12.00)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	89	83
		Mean (std)	-1.3 (13.87)	0.4 (16.15)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 50	-67, 67
Week 61	Actual	n	80	65
		Mean (std)	2.7 (7.71)	6.2 (17.78)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 33	0, 100
	Change from BL	n	78	65
		Mean (std)	-2.6 (9.37)	0.5 (17.88)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 17	-33, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	81	73
		Mean (std)	2.9 (7.40)	4.2 (7.85)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 33	0, 33
	Change from BL	n	79	72
		Mean (std)	-3.4 (12.39)	-1.1 (13.84)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 17	-33, 33
Week 73	Actual	n	76	62
		Mean (std)	4.4 (8.81)	6.7 (14.92)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 33	0, 67
	Change from BL	n	74	62
		Mean (std)	-0.7 (11.23)	1.6 (18.51)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 33	-33, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	66	58
		Mean (std)	4.8 (12.36)	5.8 (17.26)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	64	57
		Mean (std)	-0.3 (11.77)	1.2 (19.91)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 34	-33, 100
Week 85	Actual	n	70	58
		Mean (std)	3.6 (8.02)	4.3 (11.89)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 33	0, 50
	Change from BL	n	68	58
		Mean (std)	-2.2 (11.86)	-0.9 (15.74)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 33	-33, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	50
		Mean (std)	7.9 (18.65)	3.0 (8.67)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 83	0, 33
	Change from BL	n	53	49
		Mean (std)	2.8 (15.26)	-1.4 (13.08)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-33, 33
Week 97	Actual	n	65	52
		Mean (std)	5.4 (13.30)	4.5 (12.82)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	63	52
		Mean (std)	-1.0 (14.09)	-1.0 (14.90)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 67	-33, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	10.8 (22.49)	4.2 (10.85)
		Median	0	0
		Q1, Q3	0, 17.0	0, 0
		Min, Max	0, 100	0, 50
	Change from BL	n	54	43
		Mean (std)	4.5 (15.60)	-1.2 (15.58)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-33, 50
Week 109	Actual	n	52	51
		Mean (std)	6.8 (18.74)	5.3 (10.26)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 33
	Change from BL	n	51	51
		Mean (std)	1.6 (15.75)	0.3 (14.39)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 66	-33, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	6.5 (16.67)	2.3 (7.75)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 33
	Change from BL	n	49	42
		Mean (std)	4.1 (18.79)	-4.0 (12.62)
		Median	0	0
		Q1, Q3	0, 0	-17.0, 0
		Min, Max	-33, 100	-33, 33
Week 121	Actual	n	51	50
		Mean (std)	4.3 (8.76)	4.3 (11.05)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 33	0, 50
	Change from BL	n	50	50
		Mean (std)	0.7 (9.62)	-1.0 (15.94)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-17, 33	-33, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	42
		Mean (std)	3.7 (8.64)	3.6 (9.37)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 33	0, 33
	Change from BL	n	44	42
		Mean (std)	0.4 (10.54)	-1.6 (12.61)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 33	-33, 33
Week 133	Actual	n	48	43
		Mean (std)	3.5 (9.73)	5.1 (11.24)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 50	0, 50
	Change from BL	n	46	43
		Mean (std)	-0.7 (10.00)	-0.4 (14.35)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 17	-33, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	4.4 (11.95)	4.7 (9.44)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 33
	Change from BL	n	45	36
		Mean (std)	1.5 (14.68)	-1.0 (13.79)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 67	-33, 33
Week 145	Actual	n	38	31
		Mean (std)	3.1 (11.61)	2.7 (7.59)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 33
	Change from BL	n	37	31
		Mean (std)	-0.9 (10.47)	-2.2 (13.46)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 34	-33, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	7.0 (14.01)	3.1 (8.07)
		Median	0	0
		Q1, Q3	0, 8.5	0, 0
		Min, Max	0, 50	0, 33
	Change from BL	n	35	24
		Mean (std)	2.4 (16.27)	-1.7 (13.87)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 50	-33, 33
Week 157	Actual	n	26	21
		Mean (std)	3.0 (7.90)	10.7 (16.88)
		Median	0	0
		Q1, Q3	0, 0	0, 17.0
		Min, Max	0, 33	0, 50
	Change from BL	n	26	21
		Mean (std)	-2.8 (7.82)	5.1 (20.14)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-17, 17	-17, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	6.4 (17.92)	4.9 (9.81)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 33
	Change from BL	n	21	17
		Mean (std)	2.4 (15.32)	-1.0 (13.76)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-17, 50	-33, 33
Week 169	Actual	n	17	11
		Mean (std)	6.9 (17.68)	9.2 (15.62)
		Median	0	0
		Q1, Q3	0, 0	0, 17.0
		Min, Max	0, 67	0, 50
	Change from BL	n	17	11
		Mean (std)	-2.0 (16.63)	4.6 (19.83)
		Median	0	0
		Q1, Q3	0, 0	0, 17.0
		Min, Max	-50, 34	-33, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	6.9 (13.12)	0 (0)
		Median	0	0
		Q1, Q3	0, 8.5	0, 0
		Min, Max	0, 33	0, 0
	Change from BL	n	12	11
		Mean (std)	2.7 (17.19)	-4.5 (10.73)
		Median	0	0
		Q1, Q3	-8.5, 8.5	0, 0
		Min, Max	-17, 33	-33, 0
Week 181	Actual	n	9	8
		Mean (std)	11.1 (22.05)	4.3 (7.87)
		Median	0	0
		Q1, Q3	0, 0	0, 8.5
		Min, Max	0, 50	0, 17
	Change from BL	n	9	8
		Mean (std)	-1.9 (22.73)	-2.1 (6.01)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 33	-17, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	20.0 (27.39)	0 (0)
		Median	0	0
		Q1, Q3	0, 50.0	0, 0
		Min, Max	0, 50	0, 0
	Change from BL	n	5	2
		Mean (std)	6.6 (19.03)	0 (0)
		Median	0	0
		Q1, Q3	0, 17.0	0, 0
		Min, Max	-17, 33	0, 0
Week 193	Actual	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		-17.0 (-)
		Median		-17.0
		Q1, Q3		-17.0, -17.0
		Min, Max		-17, -17
Week 205	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Nausea & Vomiting Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	1.5 (6.85)	1.2 (8.32)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	181	176
		Mean (std)	-5.3 (12.66)	-6.6 (17.41)
		Median	0	0
		Q1, Q3	-17.0, 0	0, 0
		Min, Max	-67, 50	-83, 83
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	31.0 (26.85)	27.1 (25.19)
		Median	17.0	17.0
		Q1, Q3	17.0, 50.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	176
		Mean (std)	24.0 (24.77)	19.5 (24.43)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-17, 100	-83, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	178
		Mean (std)	26.9 (24.38)	22.7 (25.54)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	179	176
		Mean (std)	23.6 (22.17)	21.4 (22.41)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	177	174
		Mean (std)	-3.8 (22.43)	-1.6 (23.71)
		Median	0	0
		Q1, Q3	-17.0, 8.0	-17.0, 16.0
		Min, Max	-67, 67	-83, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	167
		Mean (std)	22.7 (25.11)	17.3 (21.99)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	169	165
		Mean (std)	-5.0 (26.14)	-5.7 (25.34)
		Median	0	0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-83, 83	-83, 67
Week 10	Actual	n	169	158
		Mean (std)	21.1 (21.83)	20.3 (21.44)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 83
	Change from BL	n	166	156
		Mean (std)	-6.2 (26.84)	-1.4 (24.03)
		Median	0	0
		Q1, Q3	-17.0, 0	-16.0, 8.0
		Min, Max	-100, 83	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	151
		Mean (std)	23.2 (22.34)	19.4 (22.06)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	157	149
		Mean (std)	-4.0 (27.47)	-2.0 (23.98)
		Median	0	0
		Q1, Q3	-17.0, 8.5	-17.0, 16.0
		Min, Max	-100, 83	-83, 83
Week 16	Actual	n	155	151
		Mean (std)	25.5 (24.99)	21.4 (24.51)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	149
		Mean (std)	-1.9 (29.87)	-0.1 (27.10)
		Median	0	0
		Q1, Q3	-17.0, 16.0	-17.0, 17.0
		Min, Max	-100, 83	-100, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	27.6 (27.11)	21.4 (24.82)
		Median	17.0	17.0
		Q1, Q3	0, 41.5	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	153	150
		Mean (std)	0.3 (31.38)	-0.4 (26.07)
		Median	0	0
		Q1, Q3	-17.0, 17.0	-17.0, 17.0
		Min, Max	-100, 100	-67, 83
Week 25	Actual	n	140	135
		Mean (std)	26.2 (26.56)	19.9 (24.41)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	138	133
		Mean (std)	-0.3 (31.03)	-0.7 (23.87)
		Median	0	0
		Q1, Q3	-17.0, 17.0	-17.0, 16.0
		Min, Max	-83, 100	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	133
		Mean (std)	25.0 (23.57)	21.5 (27.38)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	127	132
		Mean (std)	-0.5 (29.10)	1.4 (26.01)
		Median	0	0
		Q1, Q3	-17.0, 17.0	-17.0, 17.0
		Min, Max	-83, 83	-100, 83
Week 37	Actual	n	116	107
		Mean (std)	21.5 (24.09)	21.6 (22.08)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	114	106
		Mean (std)	-2.1 (31.79)	3.1 (25.40)
		Median	0	0
		Q1, Q3	-17.0, 16.0	0, 17.0
		Min, Max	-83, 100	-100, 66

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	106	107
		Mean (std)	22.2 (22.80)	18.9 (20.71)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 83	0, 100
	Change from BL	n	105	106
		Mean (std)	-2.9 (25.18)	1.0 (21.88)
		Median	0	0
		Q1, Q3	-17.0, 0	0, 16.0
		Min, Max	-67, 67	-100, 83
Week 49	Actual	n	94	83
		Mean (std)	24.8 (26.02)	18.3 (20.85)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 83
	Change from BL	n	92	83
		Mean (std)	1.6 (29.34)	0.4 (23.32)
		Median	0	0
		Q1, Q3	-17.0, 17.0	0, 16.0
		Min, Max	-83, 83	-100, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	92	84
		Mean (std)	23.3 (21.98)	21.5 (20.75)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 83
	Change from BL	n	90	83
		Mean (std)	-1.2 (30.34)	3.1 (24.22)
		Median	0	0
		Q1, Q3	-17.0, 17.0	-16.0, 17.0
		Min, Max	-83, 100	-67, 67
Week 61	Actual	n	80	65
		Mean (std)	24.0 (23.96)	18.5 (20.36)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 83
	Change from BL	n	78	65
		Mean (std)	1.4 (29.47)	0.7 (20.67)
		Median	0	0
		Q1, Q3	-17.0, 17.0	0, 16.0
		Min, Max	-83, 67	-67, 66

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	27.4 (25.94)	22.6 (20.24)
		Median	25.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 83
	Change from BL	n	80	72
		Mean (std)	1.6 (27.13)	2.8 (23.85)
		Median	0	0
		Q1, Q3	-17.0, 17.0	-8.0, 17.0
		Min, Max	-83, 67	-67, 67
Week 73	Actual	n	76	62
		Mean (std)	23.9 (23.09)	23.4 (23.82)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	74	62
		Mean (std)	1.7 (31.04)	8.1 (24.80)
		Median	0	0
		Q1, Q3	-17.0, 17.0	0, 17.0
		Min, Max	-83, 83	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	26.1 (23.92)	17.0 (23.66)
		Median	17.0	8.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	65	57
		Mean (std)	0 (28.37)	-1.8 (23.28)
		Median	0	0
		Q1, Q3	-16.0, 17.0	-16.0, 0
		Min, Max	-83, 66	-67, 67
Week 85	Actual	n	70	58
		Mean (std)	27.5 (26.74)	23.3 (25.31)
		Median	21.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	68	58
		Mean (std)	2.0 (31.54)	5.4 (25.00)
		Median	0	0
		Q1, Q3	-17.0, 17.0	0, 17.0
		Min, Max	-83, 83	-83, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	50
		Mean (std)	25.1 (25.18)	17.4 (20.78)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	53	49
		Mean (std)	0.9 (30.86)	-0.2 (24.67)
		Median	0	0
		Q1, Q3	-17.0, 17.0	-17.0, 17.0
		Min, Max	-83, 67	-67, 67
Week 97	Actual	n	65	52
		Mean (std)	29.1 (28.56)	21.8 (21.74)
		Median	17.0	17.0
		Q1, Q3	0, 50.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	63	52
		Mean (std)	2.2 (32.71)	5.5 (24.40)
		Median	0	0
		Q1, Q3	-17.0, 17.0	0, 17.0
		Min, Max	-83, 75	-67, 83

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	27.3 (27.98)	20.8 (20.93)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	54	43
		Mean (std)	1.2 (28.70)	3.5 (20.65)
		Median	0	0
		Q1, Q3	-17.0, 17.0	0, 17.0
		Min, Max	-67, 67	-50, 50
Week 109	Actual	n	52	51
		Mean (std)	25.7 (25.18)	18.6 (21.95)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 83
	Change from BL	n	51	51
		Mean (std)	-2.6 (33.56)	2.0 (23.05)
		Median	0	0
		Q1, Q3	-33.0, 16.0	0, 17.0
		Min, Max	-67, 100	-67, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	22.9 (25.58)	23.7 (24.69)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	49	42
		Mean (std)	-1.7 (26.40)	6.7 (23.30)
		Median	0	0
		Q1, Q3	-17.0, 16.0	0, 17.0
		Min, Max	-83, 67	-67, 50
Week 121	Actual	n	51	50
		Mean (std)	23.2 (24.48)	22.9 (25.34)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	50	50
		Mean (std)	-3.4 (27.74)	5.6 (25.87)
		Median	0	0
		Q1, Q3	-17.0, 0	0, 17.0
		Min, Max	-83, 67	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	43
		Mean (std)	21.6 (23.11)	21.7 (24.50)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 83	0, 83
	Change from BL	n	44	43
		Mean (std)	-3.3 (29.46)	5.0 (23.16)
		Median	0	0
		Q1, Q3	-16.5, 17.0	0, 17.0
		Min, Max	-83, 66	-67, 50
Week 133	Actual	n	48	43
		Mean (std)	21.2 (21.57)	14.7 (15.44)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 83	0, 50
	Change from BL	n	46	43
		Mean (std)	-3.7 (27.54)	-3.5 (19.79)
		Median	0	0
		Q1, Q3	-17.0, 16.0	-17.0, 16.0
		Min, Max	-83, 66	-50, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	27.6 (26.35)	28.3 (29.19)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 50.0
		Min, Max	0, 100	0, 100
	Change from BL	n	45	36
		Mean (std)	1.5 (32.13)	13.9 (27.06)
		Median	0	0
		Q1, Q3	-17.0, 17.0	0, 33.0
		Min, Max	-83, 83	-50, 83
Week 145	Actual	n	38	31
		Mean (std)	19.3 (23.40)	15.4 (19.92)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	37	31
		Mean (std)	-1.9 (31.56)	1.4 (22.11)
		Median	0	0
		Q1, Q3	-17.0, 17.0	-17.0, 17.0
		Min, Max	-83, 83	-50, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	30.6 (28.57)	23.0 (24.94)
		Median	25.0	17.0
		Q1, Q3	0, 50.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	35	24
		Mean (std)	1.8 (31.24)	9.8 (24.91)
		Median	0	0
		Q1, Q3	-17.0, 17.0	0, 17.0
		Min, Max	-67, 83	-33, 100
Week 157	Actual	n	26	21
		Mean (std)	27.3 (23.71)	23.0 (27.01)
		Median	33.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 83	0, 83
	Change from BL	n	26	21
		Mean (std)	8.7 (30.61)	5.5 (25.94)
		Median	0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	-67, 66	-50, 50

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	26.6 (24.91)	17.6 (19.91)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 83	0, 50
	Change from BL	n	21	17
		Mean (std)	0.4 (28.18)	4.0 (18.10)
		Median	0	0
		Q1, Q3	-17.0, 17.0	0, 17.0
		Min, Max	-50, 50	-33, 33
Week 169	Actual	n	17	11
		Mean (std)	30.9 (36.01)	21.1 (18.28)
		Median	17.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 50
	Change from BL	n	17	11
		Mean (std)	5.4 (39.09)	9.0 (21.42)
		Median	0	16.0
		Q1, Q3	-33.0, 33.0	0, 33.0
		Min, Max	-50, 67	-33, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	33.3 (28.41)	15.1 (15.58)
		Median	33.0	17.0
		Q1, Q3	17.0, 41.5	0, 33.0
		Min, Max	0, 100	0, 33
	Change from BL	n	12	11
		Mean (std)	9.7 (25.09)	-3.1 (23.25)
		Median	8.0	0
		Q1, Q3	0, 17.0	-17.0, 16.0
		Min, Max	-33, 67	-50, 33
Week 181	Actual	n	9	8
		Mean (std)	37.1 (34.17)	8.4 (12.57)
		Median	33.0	0
		Q1, Q3	17.0, 67.0	0, 17.0
		Min, Max	0, 100	0, 33
	Change from BL	n	9	8
		Mean (std)	9.3 (41.63)	2.0 (10.70)
		Median	0	0
		Q1, Q3	-17.0, 17.0	0, 8.0
		Min, Max	-33, 83	-17, 17

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	53.4 (38.11)	8.5 (12.02)
		Median	67.0	8.5
		Q1, Q3	33.0, 67.0	0, 17.0
		Min, Max	0, 100	0, 17
	Change from BL	n	5	2
		Mean (std)	26.8 (38.62)	0 (0)
		Median	17.0	0
		Q1, Q3	0, 67.0	0, 0
		Min, Max	-17, 67	0, 0
Week 193	Actual	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		-17.0 (-)
		Median		-17.0
		Q1, Q3		-17.0, -17.0
		Min, Max		-17, -17
Week 205	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	6.6 (13.01)	7.1 (15.73)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	181	176
		Mean (std)	-20.7 (22.35)	-15.6 (22.61)
		Median	-17.0	-16.0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 33	-100, 67
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	56.8 (28.81)	50.3 (28.86)
		Median	50.0	50.0
		Q1, Q3	33.0, 83.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	176
		Mean (std)	29.3 (29.41)	27.7 (31.57)
		Median	33.0	33.0
		Q1, Q3	0, 50.0	0, 50.0
		Min, Max	-34, 100	-83, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	183	178
		Mean (std)	14.1 (22.41)	11.9 (23.07)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	179	176
		Mean (std)	18.0 (25.99)	13.5 (20.47)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	176	174
		Mean (std)	4.0 (20.44)	2.1 (20.59)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	166
		Mean (std)	20.2 (25.59)	15.6 (22.75)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	168	164
		Mean (std)	6.7 (24.78)	4.4 (25.43)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-100, 100	-67, 100
Week 10	Actual	n	169	156
		Mean (std)	19.0 (23.46)	15.7 (22.82)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	165	154
		Mean (std)	5.9 (27.25)	5.2 (24.44)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-100, 67	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	149
		Mean (std)	21.3 (26.37)	19.3 (24.64)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	157	147
		Mean (std)	6.9 (29.47)	8.2 (27.46)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-100, 100
Week 16	Actual	n	155	150
		Mean (std)	23.2 (26.07)	20.6 (26.93)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	151	148
		Mean (std)	7.4 (27.94)	10.3 (29.56)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	151
		Mean (std)	22.8 (26.11)	20.1 (25.26)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	149
		Mean (std)	7.4 (27.47)	8.8 (29.75)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-100, 100
Week 25	Actual	n	140	135
		Mean (std)	17.9 (24.06)	15.6 (23.74)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	137	133
		Mean (std)	3.5 (24.16)	5.3 (26.64)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-100, 100	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	128	132
		Mean (std)	19.2 (25.73)	15.3 (22.97)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	125	131
		Mean (std)	4.5 (26.77)	5.3 (23.37)
		Median	0	0
		Q1, Q3	0, 33.0	0, 16.5
		Min, Max	-100, 100	-84, 67
Week 37	Actual	n	116	107
		Mean (std)	13.4 (21.50)	13.5 (20.03)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	114	106
		Mean (std)	0.3 (23.22)	4.5 (24.11)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-100, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	105	107
		Mean (std)	16.1 (20.69)	12.7 (20.76)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	103	106
		Mean (std)	2.6 (24.47)	4.4 (22.53)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-100, 67
Week 49	Actual	n	94	83
		Mean (std)	17.3 (22.76)	12.4 (20.58)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	92	83
		Mean (std)	2.9 (26.38)	2.8 (23.34)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	91	84
		Mean (std)	15.3 (20.01)	10.4 (19.26)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	89	83
		Mean (std)	3.3 (19.43)	1.8 (20.09)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 67	-67, 67
Week 61	Actual	n	80	65
		Mean (std)	16.8 (23.64)	12.7 (19.21)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	77	65
		Mean (std)	2.8 (24.31)	4.6 (21.89)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-100, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	17.0 (21.04)	12.7 (20.44)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	80	72
		Mean (std)	5.0 (25.42)	2.7 (19.14)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-67, 100	-67, 67
Week 73	Actual	n	75	62
		Mean (std)	15.5 (24.06)	16.6 (20.64)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	72	62
		Mean (std)	4.2 (24.35)	7.0 (23.45)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-67, 100	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	16.3 (22.71)	12.0 (19.40)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	65	57
		Mean (std)	6.2 (22.68)	1.7 (21.30)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 100	-67, 67
Week 85	Actual	n	69	58
		Mean (std)	17.4 (25.99)	13.7 (21.60)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	66	58
		Mean (std)	4.1 (25.16)	3.4 (23.89)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 67	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	49
		Mean (std)	18.7 (25.48)	10.8 (17.09)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	53	48
		Mean (std)	7.6 (27.41)	0 (19.47)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-34, 100	-67, 67
Week 97	Actual	n	65	52
		Mean (std)	15.5 (20.71)	12.7 (17.54)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	62	52
		Mean (std)	3.5 (25.69)	0 (18.69)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 100	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	21.7 (27.40)	9.0 (16.56)
		Median	0	0
		Q1, Q3	0, 33.0	0, 16.5
		Min, Max	0, 100	0, 67
	Change from BL	n	54	43
		Mean (std)	7.4 (28.70)	-2.3 (18.34)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-67, 100	-67, 33
Week 109	Actual	n	52	51
		Mean (std)	19.2 (25.00)	13.0 (19.97)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	51	51
		Mean (std)	5.9 (21.82)	1.3 (20.99)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 67	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	22.2 (26.42)	17.0 (25.59)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	48	42
		Mean (std)	14.6 (24.73)	7.1 (27.10)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-33, 100	-67, 67
Week 121	Actual	n	51	50
		Mean (std)	18.8 (23.30)	14.6 (21.45)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	49	50
		Mean (std)	8.8 (22.27)	3.3 (24.54)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-33, 67	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	42
		Mean (std)	15.4 (21.94)	15.8 (25.77)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	44	42
		Mean (std)	5.3 (22.61)	3.2 (31.07)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 100	-67, 100
Week 133	Actual	n	48	43
		Mean (std)	12.4 (21.26)	13.1 (25.30)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	46	43
		Mean (std)	2.9 (21.90)	0 (21.75)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	15.8 (22.98)	12.0 (22.80)
		Median	0	0
		Q1, Q3	0, 33.0	0, 16.5
		Min, Max	0, 100	0, 67
	Change from BL	n	45	36
		Mean (std)	6.6 (24.14)	1.9 (25.14)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-34, 100	-34, 67
Week 145	Actual	n	38	31
		Mean (std)	20.1 (25.21)	10.6 (15.68)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 33
	Change from BL	n	37	31
		Mean (std)	12.6 (24.08)	6.4 (15.76)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-33, 67	-33, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	16.5 (18.58)	13.5 (23.73)
		Median	0	0
		Q1, Q3	0, 33.0	0, 28.9
		Min, Max	0, 67	0, 67
	Change from BL	n	34	24
		Mean (std)	4.8 (20.33)	9.4 (23.25)
		Median	0	0
		Q1, Q3	0, 0	0, 16.5
		Min, Max	-34, 67	-33, 67
Week 157	Actual	n	26	21
		Mean (std)	11.9 (16.76)	12.6 (19.59)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 44	0, 67
	Change from BL	n	26	21
		Mean (std)	6.8 (17.09)	4.8 (15.87)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 44	-33, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	17.3 (16.89)	9.8 (19.58)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 33	0, 67
	Change from BL	n	20	17
		Mean (std)	8.3 (14.66)	3.9 (19.90)
		Median	0	0
		Q1, Q3	0, 16.5	0, 0
		Min, Max	0, 33	-33, 34
Week 169	Actual	n	17	11
		Mean (std)	17.6 (23.93)	12.1 (22.49)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	17	11
		Mean (std)	7.8 (18.87)	3.1 (17.97)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-34, 34	-33, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	24.8 (20.70)	3.0 (9.95)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 67	0, 33
	Change from BL	n	11	11
		Mean (std)	18.1 (17.32)	-3.0 (9.95)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 34	-33, 0
Week 181	Actual	n	9	8
		Mean (std)	22.1 (23.57)	4.1 (11.67)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 67	0, 33
	Change from BL	n	9	8
		Mean (std)	11.0 (29.01)	0 (17.64)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-34, 67	-33, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	19.8 (18.07)	0 (0)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 33	0, 0
	Change from BL	n	5	2
		Mean (std)	13.2 (29.52)	0 (0)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-33, 33	0, 0
Week 193	Actual	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	3.8 (11.66)	3.3 (10.61)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	180	176
		Mean (std)	-9.9 (19.51)	-8.3 (20.91)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-100, 67	-100, 34
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	47.2 (32.50)	42.1 (30.85)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	180	176
		Mean (std)	32.6 (30.97)	30.9 (31.95)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 34.0
		Min, Max	-33, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	178
		Mean (std)	32.3 (28.94)	30.2 (28.46)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	177	176
		Mean (std)	29.6 (27.14)	27.7 (26.77)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	175	174
		Mean (std)	-3.5 (28.52)	-2.7 (30.29)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	171	165
		Mean (std)	26.7 (27.63)	23.9 (26.45)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	168	163
		Mean (std)	-6.3 (28.70)	-6.1 (29.95)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-100, 67
Week 10	Actual	n	169	157
		Mean (std)	27.9 (28.29)	23.9 (25.84)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	166	155
		Mean (std)	-4.4 (30.45)	-5.8 (32.94)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	151
		Mean (std)	27.2 (28.23)	23.2 (27.69)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	157	149
		Mean (std)	-4.0 (34.91)	-5.3 (30.25)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-100, 100
Week 16	Actual	n	155	151
		Mean (std)	26.7 (26.50)	28.5 (27.82)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	149
		Mean (std)	-5.6 (29.76)	-1.7 (32.14)
		Median	0	0
		Q1, Q3	-33.0, 0	-16.5, 0
		Min, Max	-100, 67	-100, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	151
		Mean (std)	23.8 (26.04)	24.1 (26.60)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	153	149
		Mean (std)	-8.5 (30.39)	-6.1 (29.47)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-100, 67
Week 25	Actual	n	140	134
		Mean (std)	23.8 (28.92)	22.1 (25.41)
		Median	24.8	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	138	132
		Mean (std)	-6.4 (30.14)	-7.2 (29.16)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	128	130
		Mean (std)	23.6 (28.68)	22.1 (23.21)
		Median	8.3	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	126	129
		Mean (std)	-6.6 (33.74)	-7.1 (30.26)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-100, 100
Week 37	Actual	n	116	107
		Mean (std)	20.3 (25.57)	17.8 (23.19)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	114	106
		Mean (std)	-8.7 (32.32)	-11.2 (30.40)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	105	107
		Mean (std)	18.5 (23.92)	22.5 (26.34)
		Median	0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	104	106
		Mean (std)	-13.0 (27.18)	-6.1 (32.20)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 34	-100, 100
Week 49	Actual	n	93	83
		Mean (std)	24.3 (29.95)	21.2 (22.41)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	91	83
		Mean (std)	-4.4 (34.20)	-8.9 (26.12)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	91	84
		Mean (std)	20.0 (23.74)	23.3 (24.69)
		Median	0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	89	83
		Mean (std)	-12.4 (29.12)	-6.8 (28.47)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-67, 67
Week 61	Actual	n	80	65
		Mean (std)	20.1 (24.26)	17.8 (22.05)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	78	65
		Mean (std)	-11.3 (32.96)	-12.8 (26.16)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	81	73
		Mean (std)	23.0 (25.64)	21.4 (23.84)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	79	72
		Mean (std)	-8.9 (27.69)	-7.4 (28.14)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 34	-67, 67
Week 73	Actual	n	74	62
		Mean (std)	18.6 (25.84)	20.3 (23.63)
		Median	0	16.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	72	62
		Mean (std)	-11.3 (28.56)	-8.6 (26.25)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	66	58
		Mean (std)	16.1 (25.64)	20.0 (22.46)
		Median	0	16.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	64	57
		Mean (std)	-14.0 (30.20)	-8.1 (24.66)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-67, 34
Week 85	Actual	n	70	58
		Mean (std)	16.8 (23.12)	22.4 (25.33)
		Median	0	16.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	68	58
		Mean (std)	-15.0 (32.03)	-8.6 (32.34)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	50
		Mean (std)	20.5 (22.67)	24.9 (25.28)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	53	49
		Mean (std)	-11.3 (29.96)	-4.4 (28.24)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-67, 67
Week 97	Actual	n	65	52
		Mean (std)	24.3 (28.42)	22.9 (23.35)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	63	52
		Mean (std)	-8.2 (27.67)	-8.3 (27.18)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 67	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	14.7 (22.74)	17.3 (18.19)
		Median	0	16.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	54	43
		Mean (std)	-17.0 (30.14)	-11.6 (21.66)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 33	-67, 33
Week 109	Actual	n	52	51
		Mean (std)	18.4 (21.21)	21.5 (24.78)
		Median	16.5	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	51	51
		Mean (std)	-11.8 (33.89)	-7.2 (27.69)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 67	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	20.8 (29.03)	20.0 (28.26)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	49	42
		Mean (std)	-10.9 (34.29)	-8.0 (32.76)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-67, 100
Week 121	Actual	n	50	50
		Mean (std)	15.9 (22.58)	22.9 (24.01)
		Median	0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	49	50
		Mean (std)	-13.6 (30.42)	-5.6 (30.08)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-100, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	42
		Mean (std)	13.3 (20.57)	23.7 (23.59)
		Median	0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	44	42
		Mean (std)	-21.2 (27.99)	-6.4 (26.83)
		Median	-33.0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 34	-67, 34
Week 133	Actual	n	48	43
		Mean (std)	22.8 (26.76)	20.1 (23.17)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	46	43
		Mean (std)	-10.2 (28.87)	-6.9 (24.68)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 34	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	18.7 (22.88)	21.2 (25.38)
		Median	0	16.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	45	36
		Mean (std)	-11.2 (31.85)	-12.0 (21.26)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 67	-67, 33
Week 145	Actual	n	38	31
		Mean (std)	20.1 (27.42)	14.9 (22.41)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	37	31
		Mean (std)	-13.5 (33.86)	-10.7 (21.66)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 67	-67, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	23.1 (26.22)	23.5 (20.78)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	35	24
		Mean (std)	-6.7 (30.04)	-7.0 (29.48)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 100	-67, 67
Week 157	Actual	n	26	21
		Mean (std)	20.4 (23.26)	14.2 (19.85)
		Median	16.5	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	26	21
		Mean (std)	-16.6 (30.28)	-17.4 (22.72)
		Median	-16.5	-33.0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 34	-67, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	20.5 (24.02)	13.6 (16.74)
		Median	16.5	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 33
	Change from BL	n	21	17
		Mean (std)	-14.4 (28.58)	-15.6 (26.56)
		Median	0	-33.0
		Q1, Q3	-34.0, 0	-33.0, 0
		Min, Max	-67, 33	-67, 33
Week 169	Actual	n	17	11
		Mean (std)	28.3 (28.76)	12.1 (22.49)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	17	11
		Mean (std)	-12.8 (37.12)	-21.0 (22.55)
		Median	0	-33.0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 100	-34, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	30.4 (30.03)	24.1 (21.54)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	12	11
		Mean (std)	-2.8 (33.23)	-9.1 (21.45)
		Median	0	0
		Q1, Q3	-33.0, 16.5	-33.0, 0
		Min, Max	-34, 67	-34, 33
Week 181	Actual	n	9	8
		Mean (std)	37.0 (35.22)	20.6 (17.08)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 33
	Change from BL	n	9	8
		Mean (std)	0 (50.25)	-8.4 (29.53)
		Median	-33.0	0
		Q1, Q3	-34.0, 34.0	-16.5, 0
		Min, Max	-67, 67	-67, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	53.4 (38.11)	0 (0)
		Median	67.0	0
		Q1, Q3	33.0, 67.0	0, 0
		Min, Max	0, 100	0, 0
	Change from BL	n	5	2
		Mean (std)	6.8 (43.76)	-50.0 (24.04)
		Median	0	-50.0
		Q1, Q3	-33.0, 34.0	-67.0, -33.0
		Min, Max	-34, 67	-67, -33
Week 193	Actual	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		33.0 (-)
		Median		33.0
		Q1, Q3		33.0, 33.0
		Min, Max		33, 33
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		-67.0 (-)
		Median		-67.0
		Q1, Q3		-67.0, -67.0
		Min, Max		-67, -67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	8.5 (18.89)	6.1 (15.53)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	176
		Mean (std)	-23.9 (28.65)	-23.8 (27.61)
		Median	-33.0	-33.0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-100, 67
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	56.3 (29.44)	52.4 (30.16)
		Median	67.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	176
		Mean (std)	23.8 (33.17)	22.4 (33.63)
		Median	33.0	33.0
		Q1, Q3	0, 34.0	0, 34.0
		Min, Max	-67, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	185	178
		Mean (std)	17.2 (23.56)	17.2 (24.36)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	178	176
		Mean (std)	17.1 (21.88)	15.5 (22.43)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	176	174
		Mean (std)	1.5 (25.85)	-1.1 (23.76)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-100, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	171	166
		Mean (std)	16.9 (23.51)	15.4 (21.22)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	168	164
		Mean (std)	1.0 (26.87)	-1.1 (25.40)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-100, 67
Week 10	Actual	n	168	157
		Mean (std)	17.8 (25.48)	15.0 (22.44)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	165	155
		Mean (std)	1.0 (30.17)	-0.7 (28.54)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	151
		Mean (std)	12.9 (23.99)	17.4 (26.95)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	157	149
		Mean (std)	-3.1 (29.56)	1.5 (30.15)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-100, 100
Week 16	Actual	n	155	151
		Mean (std)	14.9 (24.30)	15.9 (25.79)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	149
		Mean (std)	-2.5 (30.35)	0.2 (28.84)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	151
		Mean (std)	17.7 (25.86)	13.8 (21.78)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	153	149
		Mean (std)	1.3 (31.07)	-2.0 (27.52)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-100, 67
Week 25	Actual	n	140	135
		Mean (std)	13.3 (24.89)	12.6 (24.98)
		Median	0	0
		Q1, Q3	0, 33.0	0, 16.5
		Min, Max	0, 100	0, 100
	Change from BL	n	138	133
		Mean (std)	-3.6 (29.21)	-3.0 (29.36)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	128	131
		Mean (std)	14.7 (27.33)	11.4 (23.66)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	126	130
		Mean (std)	-1.7 (32.21)	-3.8 (28.02)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 100	-67, 100
Week 37	Actual	n	116	106
		Mean (std)	8.1 (19.40)	9.7 (20.92)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	114	105
		Mean (std)	-7.4 (24.73)	-5.4 (24.57)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	105	107
		Mean (std)	8.2 (20.00)	11.0 (20.57)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	104	106
		Mean (std)	-7.6 (26.34)	-3.3 (25.19)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 67	-67, 100
Week 49	Actual	n	94	83
		Mean (std)	11.1 (20.58)	8.4 (17.10)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	92	83
		Mean (std)	-3.1 (27.97)	-6.0 (21.54)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-67, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	91	84
		Mean (std)	7.1 (16.81)	12.6 (22.45)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	89	83
		Mean (std)	-8.0 (24.56)	1.2 (27.66)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 67	-34, 100
Week 61	Actual	n	80	65
		Mean (std)	9.5 (19.95)	9.7 (22.59)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	78	65
		Mean (std)	-5.9 (26.66)	-4.1 (26.63)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	81	73
		Mean (std)	9.0 (18.24)	14.6 (24.83)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	79	72
		Mean (std)	-10.1 (25.73)	3.7 (27.06)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 67	-33, 100
Week 73	Actual	n	75	62
		Mean (std)	10.2 (20.45)	10.7 (25.44)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	73	62
		Mean (std)	-5.0 (26.95)	-1.5 (28.49)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	66	58
		Mean (std)	9.5 (18.23)	11.4 (23.79)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	64	57
		Mean (std)	-6.7 (24.52)	-1.1 (26.64)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 67	-67, 100
Week 85	Actual	n	70	58
		Mean (std)	8.5 (15.63)	10.9 (20.12)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	68	58
		Mean (std)	-8.3 (23.89)	-1.1 (24.91)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 33	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	50
		Mean (std)	9.0 (19.67)	6.6 (16.48)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	53	49
		Mean (std)	-9.4 (24.66)	-3.4 (21.69)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 34	-67, 67
Week 97	Actual	n	65	52
		Mean (std)	12.0 (24.52)	8.9 (19.88)
		Median	0	0
		Q1, Q3	0, 16.5	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	63	52
		Mean (std)	-5.0 (28.88)	-3.2 (23.03)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	12.3 (19.46)	3.8 (12.88)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	54	43
		Mean (std)	-4.6 (22.89)	-7.7 (21.58)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-34, 67	-67, 34
Week 109	Actual	n	52	51
		Mean (std)	11.5 (20.68)	7.8 (17.08)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	51	51
		Mean (std)	-5.2 (23.36)	-3.2 (21.26)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-34, 67	-34, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	50	43
		Mean (std)	8.6 (19.94)	10.1 (26.80)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	48	42
		Mean (std)	-6.9 (27.37)	-1.5 (26.42)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-33, 100
Week 121	Actual	n	51	50
		Mean (std)	11.1 (20.74)	12.6 (21.18)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	50	50
		Mean (std)	-5.9 (29.02)	-0.6 (23.71)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 67	-34, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	42
		Mean (std)	4.4 (11.34)	6.3 (16.86)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 33	0, 67
	Change from BL	n	44	42
		Mean (std)	-10.5 (21.17)	-3.9 (23.46)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 33	-67, 67
Week 133	Actual	n	48	43
		Mean (std)	11.1 (19.83)	13.1 (24.28)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	46	43
		Mean (std)	-10.1 (23.06)	2.4 (26.56)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 34	-33, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	10.1 (19.62)	13.0 (26.81)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	45	36
		Mean (std)	-5.2 (29.12)	1.9 (25.21)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-67, 67
Week 145	Actual	n	38	31
		Mean (std)	10.5 (22.02)	9.6 (19.61)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	37	31
		Mean (std)	-6.2 (25.75)	-1.1 (26.49)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 67	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	11.1 (22.50)	5.2 (15.52)
		Median	0	0
		Q1, Q3	0, 16.5	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	35	24
		Mean (std)	-6.6 (29.94)	-3.1 (25.37)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-34, 100	-67, 67
Week 157	Actual	n	26	21
		Mean (std)	10.6 (18.93)	13.4 (20.79)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	26	21
		Mean (std)	-7.2 (27.27)	7.1 (20.00)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 33.0
		Min, Max	-34, 67	-33, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	14.2 (24.80)	5.9 (17.66)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	21	17
		Mean (std)	-9.4 (30.00)	-3.9 (16.01)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 67	-33, 33
Week 169	Actual	n	17	11
		Mean (std)	23.5 (36.83)	9.1 (21.61)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	17	11
		Mean (std)	4.0 (37.01)	-3.0 (17.80)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-34, 100	-33, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	13.8 (22.28)	3.0 (9.95)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 67	0, 33
	Change from BL	n	12	11
		Mean (std)	-10.9 (25.85)	-3.0 (17.80)
		Median	-16.5	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-33, 34	-33, 33
Week 181	Actual	n	9	8
		Mean (std)	33.3 (29.01)	12.4 (17.08)
		Median	33.0	0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 67	0, 33
	Change from BL	n	9	8
		Mean (std)	14.9 (33.96)	12.4 (17.08)
		Median	33.0	0
		Q1, Q3	0, 34.0	0, 33.0
		Min, Max	-34, 67	0, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	33.2 (40.83)	0 (0)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 0
	Change from BL	n	5	2
		Mean (std)	0 (33.00)	0 (0)
		Median	0	0
		Q1, Q3	-33.0, 33.0	0, 0
		Min, Max	-33, 33	0, 0
Week 193	Actual	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	-33.0 (-)	
		Median	-33.0	
		Q1, Q3	-33.0, -33.0	
		Min, Max	-33, -33	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		33.0 (-)
		Median		33.0
		Q1, Q3		33.0, 33.0
		Min, Max		33, 33
	Change from BL	n	0	1
		Mean (std)		33.0 (-)
		Median		33.0
		Q1, Q3		33.0, 33.0
		Min, Max		33, 33
Week 205	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	2.5 (11.24)	3.0 (13.84)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	176
		Mean (std)	-13.9 (22.45)	-13.8 (24.01)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 34	-100, 67
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	48.7 (32.96)	47.9 (34.61)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	176
		Mean (std)	32.1 (34.56)	31.3 (34.97)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 34.0
		Min, Max	-34, 100	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	177
		Mean (std)	14.1 (24.19)	13.3 (21.98)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	178	176
		Mean (std)	21.4 (26.59)	18.6 (24.97)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	176	173
		Mean (std)	7.7 (28.19)	5.7 (26.48)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	171	166
		Mean (std)	21.8 (28.09)	18.6 (26.33)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	168	163
		Mean (std)	8.3 (32.38)	5.1 (27.36)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-67, 100
Week 10	Actual	n	169	157
		Mean (std)	19.0 (25.36)	16.7 (25.19)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	166	154
		Mean (std)	4.6 (30.87)	3.2 (29.47)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	151
		Mean (std)	17.8 (25.97)	15.8 (25.49)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	157	148
		Mean (std)	3.9 (29.83)	3.1 (27.88)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-100, 100	-67, 100
Week 16	Actual	n	155	151
		Mean (std)	18.2 (23.76)	15.4 (24.56)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	148
		Mean (std)	3.9 (29.97)	2.9 (27.23)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-100, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	151
		Mean (std)	17.0 (26.82)	11.2 (21.26)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	153	148
		Mean (std)	2.4 (30.91)	-2.0 (25.20)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-67, 67
Week 25	Actual	n	140	134
		Mean (std)	12.5 (22.37)	11.1 (24.12)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	138	131
		Mean (std)	-2.9 (24.96)	-1.0 (28.31)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	128	131
		Mean (std)	13.2 (22.12)	10.1 (20.27)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	126	129
		Mean (std)	-1.4 (27.06)	-3.4 (23.58)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-67, 67
Week 37	Actual	n	116	107
		Mean (std)	10.7 (19.90)	10.4 (19.62)
		Median	0	0
		Q1, Q3	0, 33.0	0, 16.5
		Min, Max	0, 100	0, 67
	Change from BL	n	114	105
		Mean (std)	-1.6 (25.08)	-2.0 (24.20)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	105	106
		Mean (std)	10.4 (20.70)	10.5 (21.47)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	104	104
		Mean (std)	-4.5 (28.20)	-2.4 (26.39)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-67, 100
Week 49	Actual	n	94	83
		Mean (std)	12.4 (24.39)	8.8 (16.45)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	92	82
		Mean (std)	-1.8 (28.93)	-4.9 (19.67)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-67, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	90	83
		Mean (std)	11.4 (22.41)	10.8 (18.80)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	88	81
		Mean (std)	-4.9 (28.39)	-2.5 (25.13)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-67, 67
Week 61	Actual	n	80	65
		Mean (std)	10.4 (20.22)	9.7 (21.84)
		Median	0	0
		Q1, Q3	0, 16.5	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	78	64
		Mean (std)	-4.3 (29.59)	-4.1 (23.36)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	81	73
		Mean (std)	13.1 (23.35)	12.7 (21.94)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	79	71
		Mean (std)	-5.5 (28.43)	-0.5 (24.88)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-100, 67	-67, 100
Week 73	Actual	n	76	62
		Mean (std)	12.7 (23.73)	10.2 (23.03)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	74	61
		Mean (std)	-4.9 (30.04)	-2.2 (19.95)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-67, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	66	58
		Mean (std)	14.6 (25.58)	10.9 (21.03)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	64	56
		Mean (std)	-5.7 (28.84)	-1.2 (27.67)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-100, 67	-67, 100
Week 85	Actual	n	70	58
		Mean (std)	7.8 (16.17)	10.9 (21.96)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	68	57
		Mean (std)	-9.6 (28.44)	-2.3 (23.42)
		Median	0	0
		Q1, Q3	-16.5, 0	0, 0
		Min, Max	-100, 34	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	50
		Mean (std)	14.5 (27.79)	10.3 (18.05)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	53	48
		Mean (std)	-5.0 (30.97)	0.3 (23.91)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-100, 67	-67, 67
Week 97	Actual	n	65	52
		Mean (std)	14.6 (25.61)	9.6 (17.83)
		Median	0	0
		Q1, Q3	0, 33.0	0, 16.5
		Min, Max	0, 100	0, 67
	Change from BL	n	63	51
		Mean (std)	-4.0 (36.02)	-4.6 (21.10)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-100, 100	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	43
		Mean (std)	13.0 (21.19)	4.6 (11.57)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 67	0, 33
	Change from BL	n	54	41
		Mean (std)	-4.0 (32.57)	-5.7 (19.54)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-67, 33
Week 109	Actual	n	52	51
		Mean (std)	8.9 (20.98)	9.1 (16.34)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	51	50
		Mean (std)	-7.9 (31.03)	-4.0 (17.32)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-67, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	9.1 (23.14)	10.8 (21.51)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	49	41
		Mean (std)	-8.2 (28.47)	0.9 (24.14)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-100, 67	-67, 67
Week 121	Actual	n	51	50
		Mean (std)	15.0 (25.24)	8.9 (16.13)
		Median	0	0
		Q1, Q3	0, 33.0	0, 16.5
		Min, Max	0, 100	0, 67
	Change from BL	n	50	49
		Mean (std)	-4.7 (27.83)	-2.4 (24.97)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 34	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	42
		Mean (std)	8.8 (19.25)	8.7 (19.58)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	44	41
		Mean (std)	-8.3 (27.96)	-4.0 (21.36)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-100, 67	-67, 67
Week 133	Actual	n	48	43
		Mean (std)	9.7 (18.09)	7.7 (14.11)
		Median	0	0
		Q1, Q3	0, 16.5	0, 0
		Min, Max	0, 67	0, 33
	Change from BL	n	46	42
		Mean (std)	-5.8 (30.12)	-4.8 (18.92)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-67, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	7.2 (17.07)	12.9 (22.87)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	45	35
		Mean (std)	-6.7 (26.22)	1.9 (22.69)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 34	-34, 67
Week 145	Actual	n	38	31
		Mean (std)	10.5 (22.02)	6.9 (13.32)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 33
	Change from BL	n	37	30
		Mean (std)	-5.4 (24.17)	-2.8 (18.55)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 34	-67, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	6.4 (13.25)	5.5 (21.22)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 33	0, 100
	Change from BL	n	35	24
		Mean (std)	-5.7 (26.09)	-1.3 (24.95)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 33	-33, 100
Week 157	Actual	n	26	21
		Mean (std)	11.0 (15.56)	11.0 (19.20)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 33	0, 67
	Change from BL	n	26	21
		Mean (std)	-5.5 (30.65)	-4.8 (19.08)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-100, 33	-67, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	4.0 (14.88)	13.7 (23.78)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	21	17
		Mean (std)	-7.1 (29.14)	-3.9 (16.27)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-34, 34
Week 169	Actual	n	17	11
		Mean (std)	7.9 (22.25)	12.1 (22.49)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	17	11
		Mean (std)	-13.5 (35.49)	-6.0 (29.18)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-67, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	8.3 (14.92)	15.1 (22.91)
		Median	0	0
		Q1, Q3	0, 16.5	0, 33.0
		Min, Max	0, 33	0, 67
	Change from BL	n	12	11
		Mean (std)	-8.3 (25.09)	6.1 (20.20)
		Median	0	0
		Q1, Q3	-16.5, 0	0, 0
		Min, Max	-67, 33	0, 67
Week 181	Actual	n	9	8
		Mean (std)	14.8 (33.77)	12.5 (24.87)
		Median	0	0
		Q1, Q3	0, 0	0, 16.5
		Min, Max	0, 100	0, 67
	Change from BL	n	9	8
		Mean (std)	-3.6 (30.91)	-4.1 (21.15)
		Median	0	0
		Q1, Q3	-33.0, 0	-16.5, 0
		Min, Max	-33, 67	-33, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	20.0 (29.91)	0 (0)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 67	0, 0
	Change from BL	n	5	2
		Mean (std)	13.4 (37.98)	-16.5 (23.33)
		Median	0	-16.5
		Q1, Q3	0, 33.0	-33.0, 0
		Min, Max	-33, 67	-33, 0
Week 193	Actual	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		-33.0 (-)
		Median		-33.0
		Q1, Q3		-33.0, -33.0
		Min, Max		-33, -33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	2.5 (11.24)	2.6 (10.83)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	175
		Mean (std)	-11.4 (25.43)	-10.4 (23.11)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-100, 100
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	47.8 (31.21)	41.3 (31.85)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	175
		Mean (std)	33.7 (30.71)	28.4 (31.86)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 34.0
		Min, Max	-67, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	178
		Mean (std)	7.7 (16.75)	6.7 (14.68)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
Week 4	Actual	n	179	175
		Mean (std)	12.6 (21.68)	7.8 (16.17)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	177	173
		Mean (std)	5.3 (21.21)	1.2 (16.98)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 100	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	167
		Mean (std)	7.6 (15.68)	7.8 (19.66)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	169	165
		Mean (std)	0.7 (18.83)	1.4 (20.58)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-34, 100
Week 10	Actual	n	169	158
		Mean (std)	7.2 (16.69)	7.3 (17.04)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	166	156
		Mean (std)	0.5 (19.71)	1.1 (19.39)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 100	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	151
		Mean (std)	8.3 (17.03)	8.7 (16.92)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	157	149
		Mean (std)	1.7 (21.51)	3.0 (19.87)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-67, 67
Week 16	Actual	n	155	150
		Mean (std)	8.3 (16.31)	8.4 (18.15)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	152	148
		Mean (std)	1.5 (18.87)	2.0 (18.67)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-67, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	8.2 (16.93)	7.6 (16.43)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 84
	Change from BL	n	153	150
		Mean (std)	1.8 (18.13)	1.8 (18.37)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-67, 67
Week 25	Actual	n	140	134
		Mean (std)	7.6 (15.46)	8.9 (19.22)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	138	132
		Mean (std)	0.7 (18.46)	2.8 (20.14)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-34, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	128	133
		Mean (std)	6.1 (16.92)	7.6 (15.63)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	126	132
		Mean (std)	-1.2 (21.24)	1.6 (17.83)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-34, 67
Week 37	Actual	n	114	108
		Mean (std)	4.4 (12.91)	7.8 (17.97)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	112	107
		Mean (std)	-2.4 (18.22)	1.7 (20.65)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-34, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	106	106
		Mean (std)	8.7 (15.18)	6.4 (17.28)
		Median	0	0
		Q1, Q3	0, 16.5	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	105	105
		Mean (std)	2.5 (22.48)	0.2 (22.14)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-34, 100
Week 49	Actual	n	93	82
		Mean (std)	6.2 (14.67)	10.9 (21.58)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	91	82
		Mean (std)	-0.5 (21.08)	4.9 (22.85)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-34, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	92	83
		Mean (std)	7.9 (18.07)	6.4 (15.99)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	90	82
		Mean (std)	2.2 (22.77)	-0.8 (19.53)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-34, 67
Week 61	Actual	n	80	65
		Mean (std)	7.4 (14.88)	9.7 (22.59)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	78	65
		Mean (std)	0 (17.76)	4.1 (25.96)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-33, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	7.3 (14.74)	6.4 (16.34)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	80	72
		Mean (std)	1.7 (20.35)	0 (16.76)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-33, 67
Week 73	Actual	n	75	62
		Mean (std)	6.6 (17.28)	8.8 (20.38)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	73	62
		Mean (std)	0 (18.29)	2.5 (21.26)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-33, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	7.9 (18.37)	4.0 (10.84)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 33
	Change from BL	n	65	57
		Mean (std)	1.5 (22.30)	-1.7 (14.52)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-33, 33
Week 85	Actual	n	70	58
		Mean (std)	9.0 (21.90)	8.0 (16.84)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	68	58
		Mean (std)	1.5 (23.30)	2.3 (17.40)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-33, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	50
		Mean (std)	12.1 (25.14)	8.0 (19.66)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	53	49
		Mean (std)	8.2 (26.03)	2.7 (23.32)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 100	-33, 100
Week 97	Actual	n	64	52
		Mean (std)	14.3 (22.36)	6.3 (13.13)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 33
	Change from BL	n	62	52
		Mean (std)	7.3 (25.62)	-0.6 (13.85)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-33, 100	-33, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	8.4 (19.70)	6.8 (19.77)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	54	43
		Mean (std)	4.3 (20.16)	1.6 (22.89)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 100	-33, 100
Week 109	Actual	n	52	51
		Mean (std)	8.9 (14.78)	5.2 (13.89)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 33	0, 67
	Change from BL	n	51	51
		Mean (std)	3.9 (19.41)	-0.6 (18.10)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 33	-33, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	4.5 (13.33)	6.9 (15.47)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	49	42
		Mean (std)	0 (19.13)	1.6 (20.63)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-33, 67
Week 121	Actual	n	51	50
		Mean (std)	12.4 (23.04)	4.0 (15.96)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	50	50
		Mean (std)	7.3 (24.48)	-1.3 (21.14)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-33, 100	-33, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	43
		Mean (std)	10.3 (15.45)	6.9 (15.47)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 33	0, 67
	Change from BL	n	44	43
		Mean (std)	6.0 (16.34)	0.8 (19.79)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 33	-33, 67
Week 133	Actual	n	48	43
		Mean (std)	10.4 (20.75)	9.2 (19.60)
		Median	0	0
		Q1, Q3	0, 16.5	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	46	43
		Mean (std)	6.5 (20.56)	3.9 (21.96)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 100	-33, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	45	36
		Mean (std)	5.1 (12.10)	9.2 (17.04)
		Median	0	0
		Q1, Q3	0, 0	0, 16.5
		Min, Max	0, 33	0, 67
	Change from BL	n	44	36
		Mean (std)	0.8 (16.67)	2.8 (18.34)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 33	-33, 34
Week 145	Actual	n	38	31
		Mean (std)	11.3 (20.81)	6.4 (13.25)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 33
	Change from BL	n	37	31
		Mean (std)	8.9 (22.98)	4.3 (14.11)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-33, 100	-33, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	12.9 (26.74)	7.3 (17.62)
		Median	0	0
		Q1, Q3	0, 16.5	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	35	24
		Mean (std)	5.7 (29.68)	4.5 (20.95)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-33, 67
Week 157	Actual	n	26	21
		Mean (std)	6.4 (16.37)	6.3 (16.98)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	26	21
		Mean (std)	1.3 (21.97)	4.7 (19.00)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-33, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	9.5 (18.65)	1.9 (8.00)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 33
	Change from BL	n	21	17
		Mean (std)	4.8 (21.75)	0 (11.67)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-33, 33
Week 169	Actual	n	17	11
		Mean (std)	15.6 (33.56)	18.2 (27.42)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	17	11
		Mean (std)	5.9 (29.39)	12.2 (26.98)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-33, 67	-33, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	19.3 (29.96)	6.1 (20.20)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	12	11
		Mean (std)	13.8 (29.97)	3.1 (10.25)
		Median	0	0
		Q1, Q3	0, 16.5	0, 0
		Min, Max	0, 100	0, 34
Week 181	Actual	n	9	8
		Mean (std)	14.7 (17.39)	4.1 (11.67)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 33	0, 33
	Change from BL	n	9	8
		Mean (std)	3.7 (19.83)	4.1 (11.67)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 33	0, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	46.6 (18.62)	0 (0)
		Median	33.0	0
		Q1, Q3	33.0, 67.0	0, 0
		Min, Max	33, 67	0, 0
	Change from BL	n	5	2
		Mean (std)	26.8 (28.03)	0 (0)
		Median	33.0	0
		Q1, Q3	0, 34.0	0, 0
		Min, Max	0, 67	0, 0
Week 193	Actual	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	0.2 (2.43)	1.1 (5.97)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 33	0, 33
	Change from BL	n	181	176
		Mean (std)	-6.8 (14.71)	-5.6 (13.46)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 0	-67, 33
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	36.7 (30.16)	34.4 (32.51)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	176
		Mean (std)	29.6 (30.85)	27.8 (33.47)
		Median	33.0	33.0
		Q1, Q3	0, 34.0	0, 33.0
		Min, Max	-34, 100	-34, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	185	178
		Mean (std)	15.3 (25.05)	15.3 (27.00)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	178	176
		Mean (std)	16.6 (26.39)	13.4 (22.63)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	175	174
		Mean (std)	1.0 (19.04)	-1.7 (21.06)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-100, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	166
		Mean (std)	15.3 (25.57)	10.6 (19.74)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	168	164
		Mean (std)	-0.8 (18.93)	-4.3 (22.18)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 34	-100, 34
Week 10	Actual	n	168	158
		Mean (std)	15.6 (26.01)	11.8 (20.96)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	164	156
		Mean (std)	-1.0 (21.98)	-1.9 (21.84)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-100, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	150
		Mean (std)	16.2 (27.22)	12.2 (23.61)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	156	148
		Mean (std)	0 (23.04)	-2.5 (24.32)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-100, 67
Week 16	Actual	n	155	149
		Mean (std)	16.3 (24.69)	13.6 (24.21)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	147
		Mean (std)	0.2 (22.18)	-1.6 (24.46)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-100, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	16.8 (24.88)	13.5 (24.73)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	150
		Mean (std)	0.9 (23.36)	-1.8 (22.34)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-100, 67
Week 25	Actual	n	140	135
		Mean (std)	15.9 (25.11)	12.5 (24.03)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	137	133
		Mean (std)	0.2 (19.99)	-0.2 (22.63)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-100, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	132
		Mean (std)	17.2 (25.71)	13.2 (22.42)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	127	131
		Mean (std)	-0.5 (21.77)	-0.6 (23.60)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-100, 67
Week 37	Actual	n	114	107
		Mean (std)	14.7 (26.58)	9.9 (17.66)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	112	106
		Mean (std)	-1.0 (21.20)	-1.6 (23.06)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-100, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	106	107
		Mean (std)	15.0 (27.64)	11.3 (21.89)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	105	106
		Mean (std)	-2.2 (19.67)	-2.0 (25.19)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-100, 67
Week 49	Actual	n	94	83
		Mean (std)	14.8 (25.66)	10.4 (22.06)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	92	83
		Mean (std)	-1.4 (24.63)	-2.4 (28.44)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-100, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	92	84
		Mean (std)	13.0 (23.13)	13.4 (23.18)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	90	83
		Mean (std)	-3.7 (23.09)	2.0 (21.66)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 67	-100, 67
Week 61	Actual	n	80	65
		Mean (std)	14.5 (25.29)	9.2 (20.83)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	78	65
		Mean (std)	-2.6 (23.19)	-3.1 (23.35)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-100, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	15.0 (26.77)	11.8 (23.17)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	80	72
		Mean (std)	-0.4 (23.38)	-2.8 (27.87)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-100, 67
Week 73	Actual	n	76	62
		Mean (std)	14.0 (25.11)	9.7 (22.10)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	74	62
		Mean (std)	-2.6 (25.73)	-0.5 (20.39)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-100, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	19.3 (29.10)	13.2 (25.76)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	65	57
		Mean (std)	2.1 (24.85)	-1.7 (26.30)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 67	-100, 67
Week 85	Actual	n	70	57
		Mean (std)	17.6 (29.91)	10.5 (19.03)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	68	57
		Mean (std)	-2.9 (30.33)	-1.2 (22.64)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-100, 67	-100, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	55	50
		Mean (std)	12.7 (21.70)	9.9 (20.42)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	53	49
		Mean (std)	-3.7 (27.38)	-2.1 (23.90)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-100, 33
Week 97	Actual	n	65	52
		Mean (std)	12.8 (23.33)	7.7 (16.94)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	63	52
		Mean (std)	-4.2 (21.93)	-1.9 (20.18)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-100, 33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	21.1 (28.96)	9.8 (22.24)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	54	43
		Mean (std)	0 (32.36)	-3.9 (22.03)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-100, 67	-100, 34
Week 109	Actual	n	52	51
		Mean (std)	14.7 (23.23)	7.8 (17.08)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	51	51
		Mean (std)	-1.9 (24.39)	-2.0 (20.47)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-34, 67	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	50	43
		Mean (std)	17.3 (30.33)	14.0 (28.43)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	48	42
		Mean (std)	-0.6 (31.07)	-0.8 (29.90)
		Median	0	0
		Q1, Q3	-16.5, 0	0, 0
		Min, Max	-100, 100	-100, 100
Week 121	Actual	n	51	50
		Mean (std)	15.6 (20.34)	13.3 (23.31)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	50	50
		Mean (std)	-0.7 (19.50)	4.0 (23.99)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 34	-67, 67

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	43
		Mean (std)	20.7 (28.70)	9.3 (19.70)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	44	43
		Mean (std)	0.8 (25.30)	-0.8 (24.63)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-100, 67
Week 133	Actual	n	48	43
		Mean (std)	18.7 (29.09)	6.2 (14.95)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	46	43
		Mean (std)	-1.4 (26.14)	-4.7 (22.56)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-33, 67	-67, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	14.5 (28.67)	7.4 (18.02)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	45	36
		Mean (std)	-3.6 (26.71)	-2.8 (20.16)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-67, 34
Week 145	Actual	n	38	31
		Mean (std)	20.9 (25.00)	7.0 (18.18)
		Median	16.5	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	37	31
		Mean (std)	1.9 (23.42)	-5.9 (22.96)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-100, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
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Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	11.1 (23.91)	6.9 (16.95)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	35	24
		Mean (std)	-10.4 (26.48)	1.4 (15.41)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 67	-33, 34
Week 157	Actual	n	26	21
		Mean (std)	20.5 (31.39)	6.3 (17.07)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	26	21
		Mean (std)	2.7 (26.51)	-3.1 (20.71)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-33, 34

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	14.2 (27.01)	7.8 (14.43)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 33
	Change from BL	n	21	17
		Mean (std)	-4.7 (15.78)	1.9 (18.34)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 33	-33, 33
Week 169	Actual	n	17	11
		Mean (std)	27.4 (39.51)	0 (0)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 0
	Change from BL	n	17	11
		Mean (std)	2.0 (24.83)	-6.0 (13.35)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-33, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	5.6 (19.34)	3.0 (9.95)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 33
	Change from BL	n	12	11
		Mean (std)	-8.3 (14.92)	-3.0 (9.95)
		Median	0	0
		Q1, Q3	-16.5, 0	0, 0
		Min, Max	-33, 0	-33, 0
Week 181	Actual	n	9	8
		Mean (std)	29.6 (35.17)	0 (0)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 0
	Change from BL	n	9	8
		Mean (std)	-7.3 (43.44)	-8.3 (15.28)
		Median	0	0
		Q1, Q3	0, 0	-16.5, 0
		Min, Max	-100, 67	-33, 0

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	33.4 (47.20)	0 (0)
		Median	0	0
		Q1, Q3	0, 67.0	0, 0
		Min, Max	0, 100	0, 0
	Change from BL	n	5	2
		Mean (std)	-13.2 (18.07)	-16.5 (23.33)
		Median	0	-16.5
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-33, 0	-33, 0
Week 193	Actual	n	1	0
		Mean (std)	0 (-)	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	-33.0 (-)	
		Median	-33.0	
		Q1, Q3	-33.0, -33.0	
		Min, Max	-33, -33	

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		0 (-)
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		-33.0 (-)
		Median		-33.0
		Q1, Q3		-33.0, -33.0
		Min, Max		-33, -33

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1002 Summary of Actual and Change from Baseline in EORTC-QLQ-C30 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial difficulties Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	5.0 (15.11)	4.1 (11.47)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	180	176
		Mean (std)	-10.5 (21.86)	-11.3 (25.13)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-100, 34	-100, 33
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	34.5 (33.91)	30.5 (33.84)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	180	176
		Mean (std)	18.9 (25.72)	14.8 (28.96)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-34, 100	-100, 100

Note: n for 'Actual' is number of subjects with non-missing values at the analysis timepoint. n for 'Change from BL' is number of subjects with non-missing values at both baseline and the analysis timepoint.
Note: For subjects with more than one assessment within the same analysis timepoint, the arithmetic mean value of the assessments within the timepoint is used for analyses.
Program: t_2_1002_c30_cfb.sas, Output: t_2_1002_c30_cfb.rtf, Generated on: 26JUL2024 17:24,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	175	168
		Mean (std)	10.6 (19.86)	9.1 (17.69)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	170	166
		Mean (std)	8.8 (18.29)	10.3 (19.58)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	161	159
		Mean (std)	-2.0 (18.86)	1.4 (15.17)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-34, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	161	154
		Mean (std)	11.7 (20.85)	11.4 (20.27)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	155	147
		Mean (std)	0 (22.12)	2.0 (15.63)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-33, 67
Week 10	Actual	n	159	145
		Mean (std)	11.5 (20.49)	10.6 (19.06)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	150	138
		Mean (std)	-0.4 (19.67)	1.8 (14.07)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-33, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	147	140
		Mean (std)	10.4 (22.32)	10.2 (18.64)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	138	133
		Mean (std)	-1.9 (21.21)	0.7 (13.79)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-34, 34
Week 16	Actual	n	141	133
		Mean (std)	8.7 (19.33)	11.2 (19.57)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	133	126
		Mean (std)	-3.5 (20.57)	1.1 (14.48)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-34, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	141	133
		Mean (std)	9.8 (20.47)	13.2 (23.08)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	133	126
		Mean (std)	-3.1 (19.65)	3.7 (20.40)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-34, 100
Week 25	Actual	n	128	122
		Mean (std)	12.2 (22.03)	13.6 (22.13)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	123	117
		Mean (std)	0 (21.34)	4.6 (18.43)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	119	118
		Mean (std)	14.3 (21.63)	13.8 (21.00)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	114	114
		Mean (std)	0.1 (18.33)	2.9 (19.55)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-34, 67
Week 37	Actual	n	106	96
		Mean (std)	13.8 (23.85)	15.9 (23.66)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	101	92
		Mean (std)	1.7 (23.72)	6.9 (18.81)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	98	94
		Mean (std)	16.9 (24.96)	12.4 (20.72)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	95	90
		Mean (std)	5.3 (23.52)	3.0 (18.37)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-33, 67
Week 49	Actual	n	87	72
		Mean (std)	13.7 (24.64)	14.3 (22.93)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	82	70
		Mean (std)	2.8 (22.34)	3.8 (17.48)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	80	72
		Mean (std)	12.9 (23.39)	15.7 (22.32)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	76	69
		Mean (std)	0.9 (23.10)	4.3 (18.82)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-34, 67
Week 61	Actual	n	74	61
		Mean (std)	13.9 (27.02)	16.8 (24.00)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	69	58
		Mean (std)	1.0 (23.50)	8.0 (23.52)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-67, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	74	64
		Mean (std)	13.0 (23.30)	14.0 (19.46)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	71	63
		Mean (std)	-0.4 (24.90)	3.7 (20.73)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-34, 67
Week 73	Actual	n	70	55
		Mean (std)	16.1 (27.63)	13.9 (20.95)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	67	54
		Mean (std)	0.5 (22.08)	4.3 (19.37)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	62	48
		Mean (std)	14.5 (24.58)	12.4 (18.92)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	58	47
		Mean (std)	2.9 (25.94)	2.8 (18.06)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-33, 67
Week 85	Actual	n	64	53
		Mean (std)	14.5 (23.66)	11.9 (18.53)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	60	53
		Mean (std)	0 (25.34)	1.9 (17.66)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-33, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	51	44
		Mean (std)	17.0 (27.81)	13.5 (17.96)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	47	44
		Mean (std)	4.3 (26.71)	3.8 (19.12)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-33, 33
Week 97	Actual	n	59	50
		Mean (std)	14.6 (24.19)	11.9 (18.69)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	56	49
		Mean (std)	-0.6 (25.06)	3.4 (19.37)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-33, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	52	41
		Mean (std)	10.2 (20.40)	14.5 (19.72)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	50	39
		Mean (std)	-0.6 (24.74)	7.6 (22.09)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-67, 67	-33, 67
Week 109	Actual	n	47	45
		Mean (std)	15.5 (23.90)	16.9 (20.82)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	46	44
		Mean (std)	0.7 (21.71)	6.8 (20.94)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-67, 67	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	48	40
		Mean (std)	13.1 (21.38)	11.6 (17.69)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	47	38
		Mean (std)	1.4 (20.73)	1.7 (18.71)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-33, 33
Week 121	Actual	n	46	45
		Mean (std)	15.2 (26.95)	16.2 (20.82)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	44	45
		Mean (std)	-1.5 (23.82)	7.4 (19.86)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-67, 67	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	43	39
		Mean (std)	13.9 (27.45)	11.9 (19.43)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	41	38
		Mean (std)	2.5 (20.34)	3.5 (21.49)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-33, 67
Week 133	Actual	n	43	38
		Mean (std)	19.3 (30.20)	15.7 (21.53)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	41	38
		Mean (std)	2.5 (26.29)	6.1 (18.69)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	43	33
		Mean (std)	13.1 (23.13)	12.0 (18.20)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	42	33
		Mean (std)	0.8 (20.11)	2.0 (23.33)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 34	-33, 67
Week 145	Actual	n	35	27
		Mean (std)	24.7 (32.71)	22.1 (22.65)
		Median	0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	33	27
		Mean (std)	9.1 (33.71)	9.9 (24.02)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	33	23
		Mean (std)	17.1 (29.01)	19.8 (21.08)
		Median	0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	32	23
		Mean (std)	1.1 (24.63)	9.7 (22.41)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-33, 67	-33, 59
Week 157	Actual	n	24	19
		Mean (std)	13.8 (21.80)	20.0 (16.11)
		Median	0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 33
	Change from BL	n	23	19
		Mean (std)	-1.4 (18.89)	13.0 (16.11)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-67, 34	0, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	20	15
		Mean (std)	11.7 (22.40)	24.3 (23.48)
		Median	0	33.0
		Q1, Q3	0, 16.5	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	20	15
		Mean (std)	-1.6 (20.14)	13.3 (24.53)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-33, 34	-33, 67
Week 169	Actual	n	17	8
		Mean (std)	21.5 (26.26)	20.8 (24.82)
		Median	0	16.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	17	8
		Mean (std)	9.9 (25.72)	12.5 (30.49)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-33, 67	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	10
		Mean (std)	16.7 (26.67)	23.2 (22.49)
		Median	0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	12	10
		Mean (std)	-5.4 (28.00)	10.0 (22.39)
		Median	0	0
		Q1, Q3	-16.5, 0	0, 33.0
		Min, Max	-67, 34	-33, 34
Week 181	Actual	n	9	6
		Mean (std)	14.8 (24.24)	22.2 (27.27)
		Median	0	16.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	9	6
		Mean (std)	7.4 (14.77)	11.2 (40.24)
		Median	0	16.5
		Q1, Q3	0, 0	-33.0, 33.0
		Min, Max	0, 34	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	40.0 (28.09)	33.0 (0)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 33.0
		Min, Max	0, 67	33, 33
	Change from BL	n	5	2
		Mean (std)	-6.4 (43.83)	16.5 (23.33)
		Median	0	16.5
		Q1, Q3	-33.0, 34.0	0, 33.0
		Min, Max	-67, 34	0, 33
Week 193	Actual	n	1	0
		Mean (std)	0	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	0	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		33.0
		Median		33.0
		Q1, Q3		33.0, 33.0
		Min, Max		33, 33
	Change from BL	n	0	1
		Mean (std)		33.0
		Median		33.0
		Q1, Q3		33.0, 33.0
		Min, Max		33, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	180	172
		Mean (std)	2.0 (9.41)	4.0 (12.52)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	168	162
		Mean (std)	-9.3 (18.88)	-5.3 (12.75)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 0	-34, 33
Post-Baseline Maximum	Actual	n	180	172
		Mean (std)	25.5 (32.72)	23.3 (26.96)
		Median	0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	168	162
		Mean (std)	13.9 (27.89)	13.9 (23.37)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-34, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	177	169
		Mean (std)	6.8 (17.14)	5.3 (13.72)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
Week 4	Actual	n	170	165
		Mean (std)	6.8 (17.31)	5.6 (16.26)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	163	159
		Mean (std)	0 (14.29)	0.4 (15.41)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	159	153
		Mean (std)	6.3 (15.03)	5.6 (14.14)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	155	146
		Mean (std)	-1.3 (14.13)	0 (14.58)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 34	-67, 34
Week 10	Actual	n	158	143
		Mean (std)	7.1 (15.13)	6.0 (14.55)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	151	137
		Mean (std)	-0.3 (16.96)	0.2 (15.83)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 34	-67, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	144	138
		Mean (std)	5.1 (13.20)	5.8 (13.83)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	138	132
		Mean (std)	-2.9 (18.20)	0.8 (13.23)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 33	-34, 34
Week 16	Actual	n	141	132
		Mean (std)	5.7 (16.39)	6.0 (14.69)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	133	126
		Mean (std)	-1.5 (21.26)	0.3 (14.25)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-67, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	141	132
		Mean (std)	6.6 (16.37)	8.5 (19.97)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	135	126
		Mean (std)	-1.5 (19.78)	2.9 (19.75)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-34, 100
Week 25	Actual	n	127	121
		Mean (std)	8.3 (18.21)	7.1 (16.76)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	122	115
		Mean (std)	0 (15.40)	1.5 (17.83)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 33	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	119	117
		Mean (std)	10.3 (18.33)	8.8 (18.24)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	114	112
		Mean (std)	1.1 (18.10)	2.7 (17.37)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-67, 67
Week 37	Actual	n	106	94
		Mean (std)	10.3 (19.11)	9.2 (17.15)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	102	91
		Mean (std)	2.2 (20.54)	3.6 (18.84)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	96	93
		Mean (std)	13.8 (20.84)	9.6 (18.74)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	93	89
		Mean (std)	5.3 (22.69)	3.4 (17.37)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-34, 67
Week 49	Actual	n	85	71
		Mean (std)	7.8 (16.74)	9.3 (17.94)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	81	68
		Mean (std)	-0.9 (19.67)	4.4 (18.98)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 34	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	81	72
		Mean (std)	11.1 (21.72)	9.7 (22.67)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	78	68
		Mean (std)	1.7 (22.16)	2.0 (24.33)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-67, 100
Week 61	Actual	n	74	60
		Mean (std)	8.5 (19.12)	9.7 (19.41)
		Median	0	0
		Q1, Q3	0, 0	0, 8.3
		Min, Max	0, 100	0, 100
	Change from BL	n	70	56
		Mean (std)	-1.5 (22.27)	6.2 (19.14)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 34	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	72	65
		Mean (std)	8.3 (16.48)	9.2 (18.14)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	70	63
		Mean (std)	-1.0 (25.33)	3.7 (20.78)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-67, 67
Week 73	Actual	n	68	55
		Mean (std)	12.7 (23.74)	8.5 (18.38)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	66	54
		Mean (std)	0 (24.10)	3.1 (17.38)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	60	49
		Mean (std)	9.4 (18.48)	7.4 (17.01)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	56	48
		Mean (std)	1.2 (24.59)	3.5 (18.42)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-33, 67
Week 85	Actual	n	64	53
		Mean (std)	9.3 (19.21)	6.3 (16.07)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	60	53
		Mean (std)	-2.2 (26.64)	0.6 (16.64)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-67, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	51	44
		Mean (std)	11.1 (20.74)	7.5 (15.78)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	47	44
		Mean (std)	-2.2 (29.10)	3.0 (18.62)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-33, 34
Week 97	Actual	n	59	50
		Mean (std)	11.0 (18.94)	9.3 (17.82)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	56	49
		Mean (std)	2.0 (23.34)	3.4 (20.61)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-67, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	52	40
		Mean (std)	6.0 (12.67)	8.3 (18.09)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 33	0, 67
	Change from BL	n	50	38
		Mean (std)	-5.4 (22.66)	5.3 (19.72)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 33	-33, 67
Week 109	Actual	n	46	44
		Mean (std)	8.7 (19.17)	11.3 (20.25)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	45	43
		Mean (std)	-0.8 (25.14)	5.4 (20.46)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-34, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	48	40
		Mean (std)	8.3 (17.50)	5.8 (14.84)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	47	38
		Mean (std)	-3.6 (24.30)	1.8 (17.12)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-33, 34
Week 121	Actual	n	45	45
		Mean (std)	11.8 (23.74)	12.5 (20.44)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	43	45
		Mean (std)	2.3 (26.65)	6.6 (20.80)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-67, 67	-34, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	43	38
		Mean (std)	9.3 (18.26)	7.9 (18.06)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	41	37
		Mean (std)	0 (21.07)	4.5 (17.81)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-33, 67
Week 133	Actual	n	42	37
		Mean (std)	16.6 (25.78)	10.8 (20.88)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	41	37
		Mean (std)	4.9 (29.45)	6.3 (20.50)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-67, 67	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	43	31
		Mean (std)	8.5 (17.93)	10.7 (17.95)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	42	31
		Mean (std)	0.8 (20.07)	7.5 (18.60)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 34	-33, 67
Week 145	Actual	n	34	27
		Mean (std)	12.7 (21.74)	14.8 (23.29)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	33	27
		Mean (std)	-1.0 (25.73)	6.2 (27.78)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-67, 67	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	33	23
		Mean (std)	13.1 (21.96)	12.6 (20.98)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	32	23
		Mean (std)	1.0 (24.68)	8.3 (19.57)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-67, 67	-33, 59
Week 157	Actual	n	22	19
		Mean (std)	10.6 (21.58)	10.4 (15.76)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 67	0, 33
	Change from BL	n	22	19
		Mean (std)	1.5 (24.16)	5.2 (22.89)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-67, 67	-67, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	20	15
		Mean (std)	8.3 (18.32)	15.5 (24.82)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	20	15
		Mean (std)	0 (24.16)	11.1 (24.12)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-67, 34	-33, 67
Week 169	Actual	n	17	8
		Mean (std)	15.6 (20.75)	16.6 (25.23)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	17	8
		Mean (std)	11.7 (16.34)	16.6 (25.23)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 34	0, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	10
		Mean (std)	13.8 (22.28)	23.3 (27.52)
		Median	0	16.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	12	10
		Mean (std)	2.8 (30.12)	16.7 (23.65)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-67, 67	0, 67
Week 181	Actual	n	9	6
		Mean (std)	11.0 (16.50)	22.2 (27.27)
		Median	0	16.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 33	0, 67
	Change from BL	n	9	6
		Mean (std)	11.0 (16.50)	22.2 (27.27)
		Median	0	16.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 33	0, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	40.0 (28.09)	33.0 (0)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 33.0
		Min, Max	0, 67	33, 33
	Change from BL	n	5	2
		Mean (std)	20.0 (56.03)	16.5 (23.33)
		Median	33.0	16.5
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	-67, 67	0, 33
Week 193	Actual	n	1	0
		Mean (std)	0	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	0	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	179	172
		Mean (std)	1.5 (8.53)	2.1 (10.24)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	170	162
		Mean (std)	-5.9 (16.34)	-3.5 (14.64)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 0	-67, 100
Post-Baseline Maximum	Actual	n	179	172
		Mean (std)	20.4 (28.31)	17.6 (26.08)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	170	162
		Mean (std)	12.9 (23.85)	11.7 (23.28)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-34, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	37	46
		Mean (std)	31.5 (36.03)	27.5 (35.40)
		Median	33.0	0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	33	37
		Mean (std)	25.3 (31.31)	29.7 (39.92)
		Median	0	0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	19	24
		Mean (std)	-1.7 (23.43)	1.4 (18.39)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-34, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	39	37
		Mean (std)	36.7 (37.37)	31.5 (36.03)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	19	23
		Mean (std)	-0.1 (29.42)	-2.8 (19.92)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 100	-34, 34
Week 10	Actual	n	36	34
		Mean (std)	33.3 (35.68)	33.3 (37.66)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	16	20
		Mean (std)	4.1 (24.00)	-1.6 (20.14)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 67	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	29	39
		Mean (std)	34.4 (36.23)	30.8 (35.43)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	15	22
		Mean (std)	4.4 (37.59)	-4.5 (15.43)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-34, 100	-33, 33
Week 16	Actual	n	30	33
		Mean (std)	30.0 (36.50)	34.4 (32.90)
		Median	16.5	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	13	22
		Mean (std)	5.1 (42.79)	-7.5 (17.51)
		Median	0	0
		Q1, Q3	0, 0	-33.0, 0
		Min, Max	-67, 100	-34, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	32	29
		Mean (std)	33.8 (32.96)	39.1 (33.51)
		Median	33.0	33.0
		Q1, Q3	0, 41.5	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	16	17
		Mean (std)	-8.5 (51.02)	-3.9 (19.81)
		Median	0	0
		Q1, Q3	-34.0, 16.5	0, 0
		Min, Max	-100, 100	-33, 33
Week 25	Actual	n	33	28
		Mean (std)	38.3 (34.54)	39.3 (34.11)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	16	15
		Mean (std)	-4.3 (29.64)	4.5 (17.16)
		Median	0	0
		Q1, Q3	-16.5, 0	0, 0
		Min, Max	-67, 67	-33, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	40	29
		Mean (std)	32.9 (32.20)	37.9 (31.89)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	20	13
		Mean (std)	3.3 (30.56)	-5.1 (18.31)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-33, 33
Week 37	Actual	n	31	26
		Mean (std)	38.6 (31.24)	41.0 (31.81)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	13	11
		Mean (std)	5.1 (26.73)	-9.2 (33.64)
		Median	0	0
		Q1, Q3	0, 0	-33.0, 0
		Min, Max	-34, 67	-67, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	39	23
		Mean (std)	41.0 (34.67)	44.9 (31.27)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	17	9
		Mean (std)	-2.1 (40.08)	-3.8 (26.10)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-67, 33
Week 49	Actual	n	22	22
		Mean (std)	42.4 (34.50)	40.9 (30.86)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	11	8
		Mean (std)	-6.3 (46.85)	4.1 (11.67)
		Median	0	0
		Q1, Q3	-34.0, 0	0, 0
		Min, Max	-67, 100	0, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	23	15
		Mean (std)	43.4 (34.07)	39.9 (22.74)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 67
	Change from BL	n	11	6
		Mean (std)	2.9 (37.94)	-11.2 (27.35)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-34, 100	-67, 0
Week 61	Actual	n	18	15
		Mean (std)	38.8 (34.83)	46.6 (30.48)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	8	6
		Mean (std)	8.1 (29.78)	5.5 (13.47)
		Median	16.5	0
		Q1, Q3	-17.0, 33.0	0, 0
		Min, Max	-34, 34	0, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	20	15
		Mean (std)	40.0 (38.44)	53.3 (24.78)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	33.0, 67.0
		Min, Max	0, 100	33, 100
	Change from BL	n	6	5
		Mean (std)	-5.7 (38.89)	0 (23.33)
		Median	0	0
		Q1, Q3	-33.0, 33.0	0, 0
		Min, Max	-67, 33	-33, 33
Week 73	Actual	n	21	15
		Mean (std)	46.0 (35.80)	39.9 (28.86)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	7	3
		Mean (std)	4.9 (22.98)	0 (0)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-33, 34	0, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	17	9
		Mean (std)	31.4 (32.30)	51.8 (24.45)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	33.0, 67.0
		Min, Max	0, 100	33, 100
	Change from BL	n	6	3
		Mean (std)	-5.7 (32.82)	11.0 (19.05)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-67, 33	0, 33
Week 85	Actual	n	19	11
		Mean (std)	42.1 (36.67)	39.4 (25.21)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 67
	Change from BL	n	3	5
		Mean (std)	11.3 (19.63)	-13.4 (29.96)
		Median	0	0
		Q1, Q3	0, 34.0	0, 0
		Min, Max	0, 34	-67, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	15	10
		Mean (std)	53.3 (41.46)	43.3 (22.74)
		Median	67.0	33.0
		Q1, Q3	0, 100.0	33.0, 67.0
		Min, Max	0, 100	0, 67
	Change from BL	n	4	2
		Mean (std)	24.8 (57.14)	0 (0)
		Median	16.5	0
		Q1, Q3	-17.0, 66.5	0, 0
		Min, Max	-34, 100	0, 0
Week 97	Actual	n	16	12
		Mean (std)	43.6 (33.90)	44.3 (29.70)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 50.0
		Min, Max	0, 100	0, 100
	Change from BL	n	5	3
		Mean (std)	-20.0 (38.37)	11.0 (19.05)
		Median	-33.0	0
		Q1, Q3	-34.0, 0	0, 33.0
		Min, Max	-67, 34	0, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	13	9
		Mean (std)	33.3 (33.42)	40.6 (27.88)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	33.0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	6	2
		Mean (std)	0 (20.87)	0 (0)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 33	0, 0
Week 109	Actual	n	10	12
		Mean (std)	46.5 (32.32)	49.9 (22.72)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 67.0
		Min, Max	0, 100	33, 100
	Change from BL	n	1	4
		Mean (std)	0	-8.5 (41.99)
		Median	0	0
		Q1, Q3	0, 0	-33.5, 16.5
		Min, Max	0, 0	-67, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	11	6
		Mean (std)	42.4 (36.87)	44.3 (17.56)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	33.0, 67.0
		Min, Max	0, 100	33, 67
	Change from BL	n	4	1
		Mean (std)	0 (0)	0
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 0	0, 0
Week 121	Actual	n	12	13
		Mean (std)	52.8 (36.22)	46.0 (21.91)
		Median	50.0	33.0
		Q1, Q3	33.0, 83.5	33.0, 67.0
		Min, Max	0, 100	33, 100
	Change from BL	n	3	4
		Mean (std)	0 (34.00)	-8.5 (41.99)
		Median	0	0
		Q1, Q3	-34.0, 34.0	-33.5, 16.5
		Min, Max	-34, 34	-67, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	13	10
		Mean (std)	40.9 (38.90)	43.2 (35.39)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	4	3
		Mean (std)	0 (0)	-11.3 (50.95)
		Median	0	0
		Q1, Q3	0, 0	-67.0, 33.0
		Min, Max	0, 0	-67, 33
Week 133	Actual	n	17	10
		Mean (std)	60.7 (33.95)	46.5 (32.32)
		Median	67.0	33.0
		Q1, Q3	33.0, 100.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	5	2
		Mean (std)	13.2 (50.71)	16.5 (23.33)
		Median	0	16.5
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-34, 100	0, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	12	11
		Mean (std)	36.0 (41.35)	51.4 (34.64)
		Median	33.0	33.0
		Q1, Q3	0, 66.5	33.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	5	1
		Mean (std)	13.2 (50.71)	33.0
		Median	0	33.0
		Q1, Q3	0, 0	33.0, 33.0
		Min, Max	-34, 100	33, 33
Week 145	Actual	n	12	9
		Mean (std)	61.1 (34.44)	48.1 (29.56)
		Median	67.0	33.0
		Q1, Q3	33.0, 100.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	4	2
		Mean (std)	16.5 (57.93)	16.5 (23.33)
		Median	0	16.5
		Q1, Q3	-17.0, 50.0	0, 33.0
		Min, Max	-34, 100	0, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	10	6
		Mean (std)	63.3 (36.78)	55.7 (17.56)
		Median	67.0	67.0
		Q1, Q3	33.0, 100.0	33.0, 67.0
		Min, Max	0, 100	33, 67
	Change from BL	n	4	1
		Mean (std)	25.0 (50.00)	0
		Median	0	0
		Q1, Q3	0, 50.0	0, 0
		Min, Max	0, 100	0, 0
Week 157	Actual	n	7	6
		Mean (std)	52.4 (42.48)	38.8 (25.29)
		Median	67.0	33.0
		Q1, Q3	0, 100.0	33.0, 67.0
		Min, Max	0, 100	0, 67
	Change from BL	n	4	0
		Mean (std)	0 (54.71)	
		Median	0	
		Q1, Q3	-33.5, 33.5	
		Min, Max	-67, 67	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	4	5
		Mean (std)	58.5 (41.99)	53.2 (30.02)
		Median	67.0	33.0
		Q1, Q3	33.5, 83.5	33.0, 67.0
		Min, Max	0, 100	33, 100
	Change from BL	n	1	1
		Mean (std)	67.0	33.0
		Median	67.0	33.0
		Q1, Q3	67.0, 67.0	33.0, 33.0
		Min, Max	67, 67	33, 33
Week 169	Actual	n	7	4
		Mean (std)	57.1 (37.19)	66.5 (38.68)
		Median	67.0	66.5
		Q1, Q3	33.0, 100.0	33.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	3	0
		Mean (std)	33.3 (57.74)	
		Median	0	
		Q1, Q3	0, 100.0	
		Min, Max	0, 100	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	4	5
		Mean (std)	58.5 (41.99)	53.2 (30.02)
		Median	67.0	33.0
		Q1, Q3	33.5, 83.5	33.0, 67.0
		Min, Max	0, 100	33, 100
	Change from BL	n	2	1
		Mean (std)	-33.5 (47.38)	33.0
		Median	-33.5	33.0
		Q1, Q3	-67.0, 0	33.0, 33.0
		Min, Max	-67, 0	33, 33
Week 181	Actual	n	3	3
		Mean (std)	55.7 (50.95)	55.3 (38.68)
		Median	67.0	33.0
		Q1, Q3	0, 100.0	33.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	1	0
		Mean (std)	34.0	
		Median	34.0	
		Q1, Q3	34.0, 34.0	
		Min, Max	34, 34	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	4	1
		Mean (std)	66.8 (27.35)	67.0
		Median	67.0	67.0
		Q1, Q3	50.0, 83.5	67.0, 67.0
		Min, Max	33, 100	67, 67
	Change from BL	n	2	0
		Mean (std)	0 (48.08)	
		Median	0	
		Q1, Q3	-34.0, 34.0	
		Min, Max	-34, 34	
Post-Baseline Minimum	Actual	n	91	88
		Mean (std)	17.2 (25.05)	19.6 (28.44)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	29	35
		Mean (std)	-19.6 (32.87)	-9.5 (25.07)
		Median	0	0
		Q1, Q3	-34.0, 0	-33.0, 0
		Min, Max	-100, 67	-67, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Maximum	Actual	n	91	88
		Mean (std)	42.5 (40.44)	39.0 (39.28)
		Median	33.0	33.0
		Q1, Q3	0, 100.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	29	35
		Mean (std)	10.3 (33.45)	5.8 (24.98)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-34, 100	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	174
		Mean (std)	13.6 (24.19)	9.4 (19.75)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	179	176
		Mean (std)	14.7 (24.75)	12.4 (19.31)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	177	170
		Mean (std)	1.0 (19.45)	2.8 (17.04)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-83, 100	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	167
		Mean (std)	17.9 (24.27)	10.4 (16.61)
		Median	0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 83
	Change from BL	n	169	161
		Mean (std)	3.5 (25.51)	1.2 (17.36)
		Median	0	0
		Q1, Q3	0, 17.0	0, 0
		Min, Max	-83, 100	-100, 67
Week 10	Actual	n	169	158
		Mean (std)	17.9 (22.45)	12.8 (19.76)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	166	152
		Mean (std)	5.1 (21.08)	3.7 (21.83)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-67, 67	-100, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	150
		Mean (std)	17.6 (21.55)	14.9 (21.49)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	157	144
		Mean (std)	3.9 (22.91)	5.3 (23.92)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-100, 100	-100, 83
Week 16	Actual	n	155	152
		Mean (std)	21.0 (24.23)	17.6 (23.40)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	146
		Mean (std)	7.4 (25.94)	8.7 (24.50)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-67, 100	-100, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	22.5 (24.42)	16.5 (23.25)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	153	146
		Mean (std)	8.6 (26.18)	7.2 (23.51)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-100, 100	-83, 83
Week 25	Actual	n	140	135
		Mean (std)	18.7 (23.36)	14.9 (22.06)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	138	130
		Mean (std)	6.3 (23.41)	5.8 (23.60)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-83, 83	-100, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	133
		Mean (std)	18.6 (23.15)	13.0 (21.11)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	127	130
		Mean (std)	5.5 (24.01)	3.7 (21.75)
		Median	0	0
		Q1, Q3	0, 17.0	0, 16.0
		Min, Max	-67, 100	-100, 67
Week 37	Actual	n	115	108
		Mean (std)	18.6 (22.80)	13.1 (21.14)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	113	104
		Mean (std)	6.1 (21.83)	4.7 (25.16)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-67, 100	-100, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	107	107
		Mean (std)	15.7 (19.51)	11.7 (21.61)
		Median	0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 67	0, 100
	Change from BL	n	106	104
		Mean (std)	3.9 (22.15)	3.5 (25.42)
		Median	0	0
		Q1, Q3	0, 17.0	0, 0
		Min, Max	-67, 67	-100, 100
Week 49	Actual	n	94	83
		Mean (std)	19.7 (22.94)	14.0 (23.61)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 83	0, 100
	Change from BL	n	92	81
		Mean (std)	6.6 (22.62)	4.5 (27.11)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-67, 83	-100, 83

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	92	84
		Mean (std)	17.4 (20.01)	15.3 (24.99)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 25.0
		Min, Max	0, 83	0, 100
	Change from BL	n	90	82
		Mean (std)	6.6 (20.26)	6.5 (26.30)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-67, 67	-100, 83
Week 61	Actual	n	81	66
		Mean (std)	20.1 (21.07)	12.5 (22.31)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 67	0, 100
	Change from BL	n	79	64
		Mean (std)	5.4 (21.70)	5.4 (22.40)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-67, 67	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	16.5 (21.96)	12.8 (22.71)
		Median	8.5	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	80	70
		Mean (std)	4.2 (24.62)	3.8 (26.36)
		Median	0	0
		Q1, Q3	0, 17.0	0, 0
		Min, Max	-83, 67	-100, 67
Week 73	Actual	n	76	62
		Mean (std)	19.2 (24.77)	11.8 (20.10)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	74	61
		Mean (std)	6.9 (26.79)	5.7 (21.30)
		Median	0	0
		Q1, Q3	0, 17.0	0, 16.5
		Min, Max	-67, 67	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	20.5 (23.58)	14.7 (24.40)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	65	56
		Mean (std)	7.6 (25.73)	7.4 (22.20)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-67, 67	-83, 67
Week 85	Actual	n	70	58
		Mean (std)	19.1 (21.64)	15.5 (23.53)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 83	0, 100
	Change from BL	n	68	58
		Mean (std)	3.7 (27.16)	7.8 (21.25)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-67, 83	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	56	48
		Mean (std)	16.1 (21.53)	16.4 (25.61)
		Median	8.5	0
		Q1, Q3	0, 33.0	0, 25.0
		Min, Max	0, 100	0, 100
	Change from BL	n	54	48
		Mean (std)	4.1 (27.64)	10.5 (23.94)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-67, 100	-33, 83
Week 97	Actual	n	65	53
		Mean (std)	19.6 (25.18)	14.5 (25.94)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	63	52
		Mean (std)	8.1 (29.66)	6.4 (31.31)
		Median	0	0
		Q1, Q3	0, 17.0	0, 16.5
		Min, Max	-83, 100	-100, 83

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	18.2 (19.03)	11.0 (21.49)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 67	0, 100
	Change from BL	n	54	42
		Mean (std)	1.9 (23.28)	7.1 (18.72)
		Median	0	0
		Q1, Q3	0, 17.0	0, 16.0
		Min, Max	-67, 50	-33, 67
Week 109	Actual	n	52	51
		Mean (std)	17.0 (21.24)	13.5 (25.42)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	51	51
		Mean (std)	3.6 (28.70)	3.3 (28.48)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-83, 83	-100, 83

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	19.3 (23.66)	17.9 (27.04)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 83	0, 100
	Change from BL	n	49	41
		Mean (std)	2.1 (27.57)	13.9 (25.47)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-67, 67	-33, 83
Week 121	Actual	n	51	50
		Mean (std)	18.3 (25.62)	12.6 (22.61)
		Median	0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	50	49
		Mean (std)	4.4 (32.07)	6.0 (26.79)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-100, 100	-100, 83

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	41
		Mean (std)	17.1 (22.60)	15.0 (24.91)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	44	41
		Mean (std)	2.3 (30.37)	8.5 (26.31)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-83, 67	-67, 83
Week 133	Actual	n	48	43
		Mean (std)	14.9 (18.55)	19.0 (28.53)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	46	42
		Mean (std)	2.6 (28.51)	8.7 (32.72)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-100, 67	-100, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	14.5 (17.38)	17.6 (26.08)
		Median	8.5	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	45	36
		Mean (std)	-0.4 (29.37)	12.5 (24.94)
		Median	0	0
		Q1, Q3	0, 17.0	0, 25.0
		Min, Max	-83, 67	-33, 83
Week 145	Actual	n	38	31
		Mean (std)	14.5 (13.95)	8.6 (16.02)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 33	0, 67
	Change from BL	n	37	30
		Mean (std)	1.8 (26.77)	2.8 (18.59)
		Median	0	0
		Q1, Q3	0, 17.0	0, 0
		Min, Max	-100, 33	-34, 50

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	25
		Mean (std)	19.4 (21.64)	17.5 (28.64)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 21.0
		Min, Max	0, 67	0, 100
	Change from BL	n	35	25
		Mean (std)	5.3 (29.09)	9.5 (20.55)
		Median	0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	-67, 67	-33, 67
Week 157	Actual	n	26	20
		Mean (std)	17.8 (22.06)	11.8 (23.01)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	26	19
		Mean (std)	7.6 (27.28)	6.2 (18.64)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-50, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	12.4 (12.74)	14.8 (22.05)
		Median	17.0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 33	0, 67
	Change from BL	n	21	17
		Mean (std)	0.5 (16.78)	7.9 (18.76)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-34, 33	-33, 50
Week 169	Actual	n	17	11
		Mean (std)	18.6 (15.35)	15.2 (24.15)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 50	0, 67
	Change from BL	n	17	10
		Mean (std)	0.1 (22.78)	11.7 (15.83)
		Median	0	0
		Q1, Q3	-16.0, 17.0	0, 33.0
		Min, Max	-34, 33	0, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	15.3 (13.11)	16.6 (27.79)
		Median	17.0	0
		Q1, Q3	0, 25.0	0, 33.0
		Min, Max	0, 33	0, 83
	Change from BL	n	12	11
		Mean (std)	1.5 (22.98)	12.1 (22.49)
		Median	0	0
		Q1, Q3	0, 17.0	0, 33.0
		Min, Max	-50, 33	-17, 50
Week 181	Actual	n	9	8
		Mean (std)	20.3 (35.12)	12.6 (23.27)
		Median	0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 67
	Change from BL	n	9	7
		Mean (std)	0 (44.13)	7.3 (13.38)
		Median	0	0
		Q1, Q3	0, 0	0, 17.0
		Min, Max	-67, 100	0, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	20.2 (18.21)	0 (0)
		Median	17.0	0
		Q1, Q3	17.0, 17.0	0, 0
		Min, Max	0, 50	0, 0
	Change from BL	n	5	2
		Mean (std)	3.6 (13.87)	0 (0)
		Median	0	0
		Q1, Q3	0, 17.0	0, 0
		Min, Max	-16, 17	0, 0
Week 193	Actual	n	1	0
		Mean (std)	33.0	
		Median	33.0	
		Q1, Q3	33.0, 33.0	
		Min, Max	33, 33	
	Change from BL	n	1	0
		Mean (std)	33.0	
		Median	33.0	
		Q1, Q3	33.0, 33.0	
		Min, Max	33, 33	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		17.0
		Median		17.0
		Q1, Q3		17.0, 17.0
		Min, Max		17, 17
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	4.4 (13.15)	3.8 (11.70)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	172
		Mean (std)	-9.2 (20.42)	-5.7 (16.29)
		Median	0	0
		Q1, Q3	-17.0, 0	0, 0
		Min, Max	-100, 33	-100, 33
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	43.8 (30.91)	37.2 (28.59)
		Median	33.0	33.0
		Q1, Q3	17.0, 67.0	17.0, 50.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	172
		Mean (std)	30.2 (28.34)	27.8 (27.17)
		Median	33.0	17.0
		Q1, Q3	0, 50.0	16.0, 50.0
		Min, Max	-33, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	185	174
		Mean (std)	16.6 (15.90)	15.2 (16.07)
		Median	17.0	8.0
		Q1, Q3	0, 25.0	0, 25.0
		Min, Max	0, 75	0, 75
Week 4	Actual	n	178	175
		Mean (std)	17.4 (16.47)	15.3 (16.61)
		Median	17.0	8.0
		Q1, Q3	0, 25.0	0, 25.0
		Min, Max	0, 75	0, 100
	Change from BL	n	176	169
		Mean (std)	1.3 (15.20)	0.1 (15.06)
		Median	0	0
		Q1, Q3	-8.0, 8.0	-8.0, 8.0
		Min, Max	-58, 67	-50, 50

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	171	167
		Mean (std)	17.8 (17.42)	16.5 (17.19)
		Median	17.0	8.0
		Q1, Q3	0, 25.0	0, 25.0
		Min, Max	0, 83	0, 83
	Change from BL	n	168	161
		Mean (std)	1.0 (15.74)	0.8 (18.68)
		Median	0	0
		Q1, Q3	-8.0, 8.0	-8.0, 9.0
		Min, Max	-42, 50	-59, 67
Week 10	Actual	n	168	158
		Mean (std)	19.3 (19.14)	15.8 (15.81)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 25.0
		Min, Max	0, 83	0, 75
	Change from BL	n	164	152
		Mean (std)	2.3 (17.04)	1.5 (17.03)
		Median	0	0
		Q1, Q3	-8.0, 12.5	-8.0, 11.5
		Min, Max	-50, 67	-59, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	150
		Mean (std)	18.0 (19.62)	16.3 (16.05)
		Median	8.0	17.0
		Q1, Q3	0, 25.0	0, 25.0
		Min, Max	0, 83	0, 75
	Change from BL	n	156	144
		Mean (std)	1.8 (18.57)	2.6 (17.05)
		Median	0	0
		Q1, Q3	-8.0, 8.0	-8.0, 11.5
		Min, Max	-50, 59	-50, 50
Week 16	Actual	n	155	152
		Mean (std)	17.5 (19.05)	15.7 (15.76)
		Median	12.5	10.3
		Q1, Q3	0, 25.0	0, 25.0
		Min, Max	0, 100	0, 58
	Change from BL	n	151	146
		Mean (std)	0.4 (19.38)	1.0 (17.48)
		Median	0	0
		Q1, Q3	-9.0, 8.0	-8.0, 9.0
		Min, Max	-50, 67	-59, 42

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	17.5 (20.64)	13.6 (16.27)
		Median	8.0	8.0
		Q1, Q3	0, 25.0	0, 23.0
		Min, Max	0, 100	0, 84
	Change from BL	n	152	146
		Mean (std)	1.3 (20.82)	-1.8 (18.98)
		Median	0	0
		Q1, Q3	-8.0, 9.0	-9.0, 8.0
		Min, Max	-75, 67	-59, 59
Week 25	Actual	n	140	135
		Mean (std)	14.7 (17.21)	14.1 (15.73)
		Median	8.0	8.0
		Q1, Q3	0, 25.0	0, 25.0
		Min, Max	0, 83	0, 75
	Change from BL	n	138	130
		Mean (std)	-1.9 (16.57)	-0.4 (17.89)
		Median	0	0
		Q1, Q3	-9.0, 8.0	-8.0, 8.0
		Min, Max	-59, 58	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	133
		Mean (std)	13.8 (16.85)	12.7 (15.72)
		Median	8.0	8.0
		Q1, Q3	0, 25.0	0, 17.0
		Min, Max	0, 75	0, 75
	Change from BL	n	126	129
		Mean (std)	-4.1 (16.70)	-1.4 (18.05)
		Median	0	0
		Q1, Q3	-9.0, 0	-9.0, 8.0
		Min, Max	-50, 58	-67, 67
Week 37	Actual	n	115	108
		Mean (std)	11.3 (14.45)	12.8 (16.84)
		Median	8.0	8.0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 67	0, 83
	Change from BL	n	113	105
		Mean (std)	-4.2 (16.14)	-1.9 (19.49)
		Median	0	0
		Q1, Q3	-17.0, 0	-11.0, 8.0
		Min, Max	-42, 67	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	107	107
		Mean (std)	12.6 (16.04)	14.2 (17.94)
		Median	8.0	8.0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 83	0, 100
	Change from BL	n	106	104
		Mean (std)	-4.0 (17.01)	-0.5 (19.02)
		Median	0	0
		Q1, Q3	-16.0, 0	-12.5, 9.0
		Min, Max	-42, 58	-67, 67
Week 49	Actual	n	94	83
		Mean (std)	13.2 (16.14)	12.4 (16.48)
		Median	8.0	8.0
		Q1, Q3	0, 25.0	0, 17.0
		Min, Max	0, 75	0, 92
	Change from BL	n	92	81
		Mean (std)	-3.7 (17.18)	-2.0 (17.93)
		Median	0	0
		Q1, Q3	-16.0, 8.0	-11.0, 8.0
		Min, Max	-50, 50	-58, 50

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	92	84
		Mean (std)	12.0 (16.23)	14.1 (18.29)
		Median	8.0	8.0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 100	0, 92
	Change from BL	n	90	82
		Mean (std)	-4.5 (15.90)	0.2 (20.05)
		Median	0	0
		Q1, Q3	-17.0, 0	-9.0, 8.0
		Min, Max	-42, 50	-58, 75
Week 61	Actual	n	81	66
		Mean (std)	12.9 (16.53)	13.8 (16.93)
		Median	8.0	8.0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 83	0, 75
	Change from BL	n	79	64
		Mean (std)	-3.1 (17.80)	-1.2 (19.45)
		Median	0	0
		Q1, Q3	-17.0, 3.0	-16.0, 8.0
		Min, Max	-42, 42	-50, 59

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	13.5 (15.56)	11.7 (13.33)
		Median	8.0	8.0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 58	0, 67
	Change from BL	n	80	71
		Mean (std)	-4.3 (17.83)	-1.9 (15.99)
		Median	0	0
		Q1, Q3	-17.0, 0	-9.0, 8.0
		Min, Max	-50, 42	-42, 67
Week 73	Actual	n	76	62
		Mean (std)	14.2 (17.19)	14.3 (17.61)
		Median	8.0	8.0
		Q1, Q3	0, 25.0	0, 25.0
		Min, Max	0, 75	0, 75
	Change from BL	n	74	61
		Mean (std)	-1.0 (19.13)	-0.8 (17.51)
		Median	0	0
		Q1, Q3	-9.0, 8.0	-9.0, 8.0
		Min, Max	-34, 67	-59, 50

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	12.2 (16.74)	12.5 (16.97)
		Median	8.0	8.0
		Q1, Q3	0, 25.0	0, 17.0
		Min, Max	0, 75	0, 75
	Change from BL	n	65	56
		Mean (std)	-5.1 (19.80)	0.1 (18.47)
		Median	-8.0	0
		Q1, Q3	-17.0, 8.0	-12.0, 9.0
		Min, Max	-50, 50	-34, 50
Week 85	Actual	n	70	58
		Mean (std)	14.2 (17.93)	15.9 (18.43)
		Median	8.0	8.0
		Q1, Q3	0, 25.0	0, 25.0
		Min, Max	0, 83	0, 83
	Change from BL	n	68	58
		Mean (std)	-2.6 (18.14)	-0.5 (18.36)
		Median	0	0
		Q1, Q3	-17.0, 8.0	-8.0, 8.0
		Min, Max	-34, 42	-59, 66

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	56	48
		Mean (std)	10.8 (13.81)	12.2 (16.32)
		Median	8.0	8.0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 58	0, 67
	Change from BL	n	54	48
		Mean (std)	-5.3 (17.57)	-0.2 (18.02)
		Median	-4.0	0
		Q1, Q3	-17.0, 0	-8.0, 8.0
		Min, Max	-34, 58	-50, 67
Week 97	Actual	n	65	53
		Mean (std)	11.2 (12.91)	13.5 (16.13)
		Median	8.0	8.0
		Q1, Q3	0, 17.0	0, 25.0
		Min, Max	0, 50	0, 58
	Change from BL	n	63	52
		Mean (std)	-5.1 (16.58)	-1.8 (18.15)
		Median	-4.0	0
		Q1, Q3	-17.0, 0	-16.0, 9.0
		Min, Max	-42, 34	-50, 58

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	10.0 (12.45)	13.5 (17.89)
		Median	8.0	4.0
		Q1, Q3	0, 17.0	0, 25.0
		Min, Max	0, 58	0, 67
	Change from BL	n	54	42
		Mean (std)	-5.3 (17.91)	-0.9 (20.05)
		Median	-8.0	-4.0
		Q1, Q3	-17.0, 8.0	-16.0, 9.0
		Min, Max	-42, 33	-42, 67
Week 109	Actual	n	52	51
		Mean (std)	12.6 (15.17)	17.1 (21.36)
		Median	8.0	8.0
		Q1, Q3	0, 25.0	0, 33.0
		Min, Max	0, 58	0, 83
	Change from BL	n	51	51
		Mean (std)	-3.5 (17.44)	4.0 (19.48)
		Median	0	0
		Q1, Q3	-17.0, 8.0	-8.0, 8.0
		Min, Max	-34, 42	-17, 58

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	9.0 (9.91)	16.3 (20.40)
		Median	8.0	17.0
		Q1, Q3	0, 17.0	0, 25.0
		Min, Max	0, 42	0, 92
	Change from BL	n	49	41
		Mean (std)	-5.8 (14.60)	-2.1 (20.53)
		Median	-8.0	-8.0
		Q1, Q3	-16.0, 0	-16.0, 9.0
		Min, Max	-34, 25	-42, 59
Week 121	Actual	n	51	50
		Mean (std)	13.6 (15.69)	16.2 (20.38)
		Median	8.0	8.0
		Q1, Q3	0, 17.0	0, 25.0
		Min, Max	0, 58	0, 92
	Change from BL	n	50	50
		Mean (std)	-3.4 (20.09)	2.6 (23.34)
		Median	-4.0	0
		Q1, Q3	-17.0, 9.0	-8.0, 17.0
		Min, Max	-41, 50	-59, 58

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	41
		Mean (std)	8.5 (10.74)	14.4 (23.30)
		Median	0	8.0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 33	0, 100
	Change from BL	n	44	41
		Mean (std)	-6.3 (16.97)	0.4 (21.13)
		Median	-8.0	-8.0
		Q1, Q3	-12.5, 0	-9.0, 8.0
		Min, Max	-50, 33	-50, 67
Week 133	Actual	n	48	43
		Mean (std)	10.6 (13.58)	16.3 (20.18)
		Median	8.0	8.0
		Q1, Q3	0, 17.0	0, 25.0
		Min, Max	0, 42	0, 67
	Change from BL	n	46	42
		Mean (std)	-5.3 (17.46)	3.4 (21.85)
		Median	-8.0	0
		Q1, Q3	-17.0, 0	-16.0, 17.0
		Min, Max	-50, 34	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	10.1 (14.92)	13.4 (18.35)
		Median	4.0	8.0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 75	0, 84
	Change from BL	n	45	36
		Mean (std)	-3.6 (19.52)	-1.5 (15.92)
		Median	0	0
		Q1, Q3	-17.0, 0	-16.0, 8.0
		Min, Max	-34, 67	-34, 50
Week 145	Actual	n	38	31
		Mean (std)	10.1 (13.66)	12.5 (19.51)
		Median	0	8.0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 50	0, 83
	Change from BL	n	37	30
		Mean (std)	-6.6 (18.68)	1.8 (19.07)
		Median	-8.0	0
		Q1, Q3	-17.0, 0	-8.0, 8.0
		Min, Max	-34, 50	-25, 75

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	25
		Mean (std)	11.8 (15.15)	11.3 (14.56)
		Median	8.0	8.0
		Q1, Q3	0, 21.0	0, 17.0
		Min, Max	0, 67	0, 50
	Change from BL	n	35	25
		Mean (std)	-5.9 (17.87)	-2.5 (13.60)
		Median	-8.0	0
		Q1, Q3	-17.0, 8.0	-8.0, 0
		Min, Max	-42, 25	-42, 33
Week 157	Actual	n	26	20
		Mean (std)	10.8 (12.66)	9.4 (12.86)
		Median	8.0	2.0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 50	0, 42
	Change from BL	n	26	19
		Mean (std)	0 (17.64)	-2.9 (17.70)
		Median	0	0
		Q1, Q3	-16.0, 8.0	-17.0, 0
		Min, Max	-25, 50	-42, 42

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	11.3 (14.90)	12.2 (22.22)
		Median	8.0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 50	0, 83
	Change from BL	n	21	17
		Mean (std)	-2.1 (23.33)	3.2 (20.22)
		Median	0	0
		Q1, Q3	-17.0, 8.0	-8.0, 8.0
		Min, Max	-41, 50	-17, 58
Week 169	Actual	n	17	11
		Mean (std)	19.1 (21.29)	12.1 (13.55)
		Median	8.0	8.0
		Q1, Q3	0, 33.0	0, 25.0
		Min, Max	0, 67	0, 33
	Change from BL	n	17	10
		Mean (std)	4.5 (22.23)	1.6 (17.53)
		Median	0	0
		Q1, Q3	-8.0, 9.0	-17.0, 9.0
		Min, Max	-25, 59	-17, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	22.2 (29.17)	9.1 (11.48)
		Median	12.5	0
		Q1, Q3	0, 29.0	0, 25.0
		Min, Max	0, 100	0, 25
	Change from BL	n	12	11
		Mean (std)	4.9 (36.42)	-2.3 (11.44)
		Median	-8.0	0
		Q1, Q3	-17.0, 17.0	-17.0, 8.0
		Min, Max	-34, 92	-17, 17
Week 181	Actual	n	9	8
		Mean (std)	18.3 (23.77)	6.9 (8.64)
		Median	8.0	4.0
		Q1, Q3	0, 25.0	0, 12.5
		Min, Max	0, 58	0, 22
	Change from BL	n	9	7
		Mean (std)	0.8 (33.96)	-1.3 (12.38)
		Median	0	0
		Q1, Q3	-25.0, 8.0	-17.0, 8.0
		Min, Max	-42, 58	-17, 17

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	31.4 (25.25)	0 (0)
		Median	25.0	0
		Q1, Q3	8.0, 58.0	0, 0
		Min, Max	8, 58	0, 0
	Change from BL	n	5	2
		Mean (std)	18.2 (34.00)	-8.5 (12.02)
		Median	8.0	-8.5
		Q1, Q3	-8.0, 50.0	-17.0, 0
		Min, Max	-17, 58	-17, 0
Week 193	Actual	n	1	0
		Mean (std)	0	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	-33.0	
		Median	-33.0	
		Q1, Q3	-33.0, -33.0	
		Min, Max	-33, -33	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		-17.0
		Median		-17.0
		Q1, Q3		-17.0, -17.0
		Min, Max		-17, -17

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	4.9 (9.32)	4.3 (8.14)
		Median	0	0
		Q1, Q3	0, 8.0	0, 8.0
		Min, Max	0, 50	0, 50
	Change from BL	n	180	172
		Mean (std)	-11.7 (14.38)	-10.9 (15.21)
		Median	-8.0	-8.0
		Q1, Q3	-17.0, 0	-17.0, 0
		Min, Max	-75, 25	-67, 25
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	36.0 (23.53)	32.6 (21.68)
		Median	33.0	25.0
		Q1, Q3	17.0, 50.0	17.0, 42.0
		Min, Max	0, 100	0, 100
	Change from BL	n	180	172
		Mean (std)	19.3 (21.32)	17.6 (21.87)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 29.0
		Min, Max	-34, 92	-50, 75

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	173
		Mean (std)	12.9 (13.38)	11.8 (12.98)
		Median	7.0	7.0
		Q1, Q3	0, 20.0	0, 20.0
		Min, Max	0, 67	0, 67
Week 4	Actual	n	179	176
		Mean (std)	11.9 (12.93)	10.1 (10.89)
		Median	7.0	7.0
		Q1, Q3	0, 20.0	0, 16.5
		Min, Max	0, 67	0, 47
	Change from BL	n	177	169
		Mean (std)	-0.8 (11.91)	-1.6 (12.26)
		Median	0	0
		Q1, Q3	-7.0, 7.0	-7.0, 6.0
		Min, Max	-33, 40	-47, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	167
		Mean (std)	10.4 (11.45)	10.4 (11.48)
		Median	7.0	7.0
		Q1, Q3	0, 13.0	0, 13.0
		Min, Max	0, 47	0, 60
	Change from BL	n	169	160
		Mean (std)	-2.2 (13.28)	-1.5 (13.96)
		Median	0	0
		Q1, Q3	-7.0, 7.0	-7.0, 6.0
		Min, Max	-46, 33	-53, 33
Week 10	Actual	n	168	158
		Mean (std)	10.2 (12.90)	8.8 (9.44)
		Median	7.0	7.0
		Q1, Q3	0, 13.0	0, 13.0
		Min, Max	0, 67	0, 40
	Change from BL	n	165	151
		Mean (std)	-2.5 (14.42)	-2.5 (13.80)
		Median	0	0
		Q1, Q3	-13.0, 6.0	-7.0, 6.0
		Min, Max	-40, 47	-67, 40

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	150
		Mean (std)	10.9 (15.04)	10.4 (11.72)
		Median	7.0	7.0
		Q1, Q3	0, 13.0	0, 13.0
		Min, Max	0, 100	0, 60
	Change from BL	n	157	143
		Mean (std)	-1.2 (15.90)	-1.3 (15.37)
		Median	0	0
		Q1, Q3	-12.0, 6.0	-7.0, 6.0
		Min, Max	-40, 73	-53, 60
Week 16	Actual	n	155	152
		Mean (std)	10.2 (12.81)	10.2 (11.35)
		Median	7.0	7.0
		Q1, Q3	0, 20.0	0, 13.0
		Min, Max	0, 53	0, 53
	Change from BL	n	152	145
		Mean (std)	-2.1 (16.07)	-1.9 (14.43)
		Median	0	0
		Q1, Q3	-13.0, 6.0	-7.0, 6.0
		Min, Max	-47, 53	-53, 47

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	10.2 (12.56)	8.5 (10.80)
		Median	7.0	7.0
		Q1, Q3	0, 13.3	0, 13.0
		Min, Max	0, 53	0, 57
	Change from BL	n	153	145
		Mean (std)	-2.4 (15.28)	-3.2 (14.85)
		Median	0	0
		Q1, Q3	-13.0, 6.0	-7.0, 6.0
		Min, Max	-40, 40	-60, 57
Week 25	Actual	n	140	134
		Mean (std)	8.7 (11.05)	8.6 (12.51)
		Median	7.0	7.0
		Q1, Q3	0, 13.0	0, 13.0
		Min, Max	0, 60	0, 87
	Change from BL	n	138	129
		Mean (std)	-4.5 (14.14)	-2.5 (15.34)
		Median	0	0
		Q1, Q3	-13.0, 0	-7.0, 0
		Min, Max	-46, 40	-53, 87

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	133
		Mean (std)	8.9 (11.05)	9.6 (13.56)
		Median	7.0	7.0
		Q1, Q3	0, 13.0	0, 13.0
		Min, Max	0, 47	0, 93
	Change from BL	n	127	129
		Mean (std)	-3.7 (13.93)	-1.8 (16.40)
		Median	0	0
		Q1, Q3	-13.0, 0	-7.0, 6.0
		Min, Max	-47, 34	-54, 93
Week 37	Actual	n	115	107
		Mean (std)	8.9 (10.63)	8.6 (10.36)
		Median	7.0	7.0
		Q1, Q3	0, 13.0	0, 13.0
		Min, Max	0, 53	0, 53
	Change from BL	n	113	103
		Mean (std)	-2.7 (13.87)	-2.3 (13.34)
		Median	0	0
		Q1, Q3	-7.0, 6.0	-7.0, 6.0
		Min, Max	-47, 53	-53, 46

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	107	107
		Mean (std)	9.2 (11.89)	9.9 (13.86)
		Median	3.5	7.0
		Q1, Q3	0, 17.0	0, 13.0
		Min, Max	0, 40	0, 100
	Change from BL	n	106	103
		Mean (std)	-2.9 (14.46)	-1.7 (16.46)
		Median	0	0
		Q1, Q3	-13.0, 0	-7.0, 3.5
		Min, Max	-34, 33	-53, 100
Week 49	Actual	n	94	82
		Mean (std)	11.5 (16.62)	9.5 (10.23)
		Median	7.0	7.0
		Q1, Q3	0, 13.0	0, 13.0
		Min, Max	0, 93	0, 40
	Change from BL	n	92	79
		Mean (std)	-1.4 (16.23)	-1.5 (13.31)
		Median	0	0
		Q1, Q3	-10.0, 6.0	-7.0, 7.0
		Min, Max	-40, 73	-53, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	92	83
		Mean (std)	10.3 (13.60)	9.1 (10.76)
		Median	7.0	7.0
		Q1, Q3	0, 20.0	0, 13.0
		Min, Max	0, 67	0, 53
	Change from BL	n	90	80
		Mean (std)	-2.6 (13.83)	-1.5 (10.99)
		Median	0	0
		Q1, Q3	-13.0, 6.0	-7.0, 3.0
		Min, Max	-47, 46	-40, 27
Week 61	Actual	n	81	65
		Mean (std)	10.8 (11.61)	9.1 (10.90)
		Median	7.0	7.0
		Q1, Q3	0, 20.0	0, 13.0
		Min, Max	0, 47	0, 53
	Change from BL	n	79	62
		Mean (std)	-2.2 (12.92)	-1.5 (10.87)
		Median	0	0
		Q1, Q3	-12.0, 7.0	-6.0, 0
		Min, Max	-40, 27	-53, 20

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	9.6 (11.85)	8.7 (10.63)
		Median	7.0	7.0
		Q1, Q3	0, 13.0	0, 13.0
		Min, Max	0, 53	0, 67
	Change from BL	n	80	70
		Mean (std)	-3.2 (13.89)	-1.9 (8.72)
		Median	-3.0	0
		Q1, Q3	-13.0, 0	-7.0, 0
		Min, Max	-40, 53	-27, 20
Week 73	Actual	n	76	62
		Mean (std)	9.1 (11.43)	11.8 (13.26)
		Median	7.0	7.0
		Q1, Q3	0, 13.0	0, 20.0
		Min, Max	0, 40	0, 67
	Change from BL	n	74	60
		Mean (std)	-2.5 (14.40)	-0.3 (13.22)
		Median	0	0
		Q1, Q3	-13.0, 0	-6.0, 7.0
		Min, Max	-40, 33	-53, 20

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	66	58
		Mean (std)	9.9 (11.51)	8.6 (11.10)
		Median	7.0	7.0
		Q1, Q3	0, 20.0	0, 13.0
		Min, Max	0, 60	0, 47
	Change from BL	n	64	55
		Mean (std)	-1.9 (13.94)	0.3 (13.37)
		Median	0	0
		Q1, Q3	-13.0, 6.5	-6.0, 6.0
		Min, Max	-40, 60	-40, 47
Week 85	Actual	n	70	57
		Mean (std)	10.9 (13.62)	8.6 (10.62)
		Median	7.0	7.0
		Q1, Q3	0, 20.0	0, 13.0
		Min, Max	0, 53	0, 53
	Change from BL	n	68	56
		Mean (std)	-1.5 (15.08)	-2.7 (14.26)
		Median	0	0
		Q1, Q3	-13.0, 7.0	-7.0, 0
		Min, Max	-53, 40	-53, 40

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	56	48
		Mean (std)	10.6 (12.85)	9.3 (11.12)
		Median	7.0	7.0
		Q1, Q3	0, 13.0	0, 16.5
		Min, Max	0, 47	0, 40
	Change from BL	n	54	47
		Mean (std)	-1.1 (13.80)	-0.5 (7.83)
		Median	0	0
		Q1, Q3	-13.0, 7.0	-6.0, 0
		Min, Max	-27, 34	-20, 20
Week 97	Actual	n	65	53
		Mean (std)	13.9 (16.14)	10.0 (12.34)
		Median	7.0	7.0
		Q1, Q3	0, 20.0	0, 13.0
		Min, Max	0, 60	0, 53
	Change from BL	n	63	51
		Mean (std)	-0.4 (16.60)	-0.7 (12.24)
		Median	0	0
		Q1, Q3	-13.0, 13.0	-7.0, 6.0
		Min, Max	-33, 40	-27, 40

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	9.3 (13.86)	9.3 (12.01)
		Median	0	3.5
		Q1, Q3	0, 13.5	0, 20.0
		Min, Max	0, 73	0, 40
	Change from BL	n	54	41
		Mean (std)	-1.7 (14.95)	0 (11.90)
		Median	0	0
		Q1, Q3	-13.0, 6.0	-7.0, 0
		Min, Max	-40, 40	-20, 40
Week 109	Actual	n	52	51
		Mean (std)	9.3 (11.53)	10.6 (11.99)
		Median	7.0	7.0
		Q1, Q3	0, 13.0	0, 13.0
		Min, Max	0, 47	0, 47
	Change from BL	n	51	50
		Mean (std)	-3.6 (13.35)	0.9 (11.89)
		Median	0	0
		Q1, Q3	-13.0, 7.0	-6.0, 6.0
		Min, Max	-27, 20	-34, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	7.3 (12.67)	8.5 (10.30)
		Median	0	7.0
		Q1, Q3	0, 13.0	0, 13.0
		Min, Max	0, 60	0, 40
	Change from BL	n	49	40
		Mean (std)	-4.4 (12.40)	-3.0 (10.35)
		Median	0	0
		Q1, Q3	-13.0, 0	-7.0, 0
		Min, Max	-27, 27	-46, 20
Week 121	Actual	n	50	50
		Mean (std)	12.4 (14.44)	8.6 (9.92)
		Median	7.0	7.0
		Q1, Q3	0, 20.0	0, 13.0
		Min, Max	0, 53	0, 33
	Change from BL	n	49	49
		Mean (std)	-1.1 (14.81)	-2.9 (13.33)
		Median	0	0
		Q1, Q3	-13.0, 7.0	-7.0, 0
		Min, Max	-27, 46	-53, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	41
		Mean (std)	7.9 (8.99)	10.2 (11.89)
		Median	7.0	7.0
		Q1, Q3	0, 13.0	0, 20.0
		Min, Max	0, 33	0, 40
	Change from BL	n	44	40
		Mean (std)	-3.3 (12.23)	0.5 (9.51)
		Median	-3.0	0
		Q1, Q3	-10.5, 0	-6.5, 7.0
		Min, Max	-40, 27	-20, 20
Week 133	Actual	n	48	43
		Mean (std)	10.6 (14.22)	8.9 (11.52)
		Median	7.0	7.0
		Q1, Q3	0, 20.0	0, 13.0
		Min, Max	0, 60	0, 40
	Change from BL	n	46	41
		Mean (std)	-2.6 (12.44)	-2.6 (8.89)
		Median	0	0
		Q1, Q3	-13.0, 0	-7.0, 0
		Min, Max	-27, 20	-20, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	10.5 (13.46)	10.0 (11.33)
		Median	7.0	7.0
		Q1, Q3	0, 20.0	0, 16.8
		Min, Max	0, 53	0, 40
	Change from BL	n	45	35
		Mean (std)	-0.6 (13.01)	1.8 (10.87)
		Median	0	0
		Q1, Q3	-13.0, 7.0	0, 7.0
		Min, Max	-27, 27	-20, 40
Week 145	Actual	n	38	31
		Mean (std)	8.1 (12.17)	7.5 (10.91)
		Median	0	0
		Q1, Q3	0, 13.0	0, 13.0
		Min, Max	0, 47	0, 47
	Change from BL	n	37	29
		Mean (std)	-3.6 (13.18)	-2.9 (9.13)
		Median	-6.0	0
		Q1, Q3	-13.0, 0	-7.0, 0
		Min, Max	-46, 20	-20, 20

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	25
		Mean (std)	9.6 (13.73)	8.4 (11.29)
		Median	0	7.0
		Q1, Q3	0, 13.0	0, 13.0
		Min, Max	0, 53	0, 33
	Change from BL	n	35	24
		Mean (std)	-4.6 (15.66)	0.2 (13.11)
		Median	0	0
		Q1, Q3	-13.0, 0	-6.5, 7.0
		Min, Max	-53, 33	-40, 27
Week 157	Actual	n	26	20
		Mean (std)	6.2 (9.05)	11.0 (14.89)
		Median	0	3.5
		Q1, Q3	0, 13.0	0, 16.5
		Min, Max	0, 27	0, 47
	Change from BL	n	26	18
		Mean (std)	-3.9 (8.97)	1.1 (9.39)
		Median	-0.5	0
		Q1, Q3	-7.0, 0	-6.0, 0
		Min, Max	-20, 13	-14, 27

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	8.4 (9.69)	10.5 (13.09)
		Median	7.0	0
		Q1, Q3	0, 13.0	0, 20.0
		Min, Max	0, 27	0, 40
	Change from BL	n	21	16
		Mean (std)	-2.7 (16.24)	-0.5 (7.69)
		Median	0	0
		Q1, Q3	-13.0, 7.0	0, 0
		Min, Max	-46, 27	-14, 20
Week 169	Actual	n	17	11
		Mean (std)	13.4 (17.09)	15.1 (17.58)
		Median	0	7.0
		Q1, Q3	0, 27.0	0, 33.0
		Min, Max	0, 47	0, 40
	Change from BL	n	17	10
		Mean (std)	1.2 (13.85)	2.6 (9.11)
		Median	0	0
		Q1, Q3	-7.0, 7.0	0, 7.0
		Min, Max	-20, 27	-14, 20

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	11.4 (8.05)	9.7 (12.75)
		Median	13.0	7.0
		Q1, Q3	3.5, 20.0	0, 20.0
		Min, Max	0, 20	0, 40
	Change from BL	n	12	11
		Mean (std)	0.8 (11.37)	2.5 (8.49)
		Median	3.0	0
		Q1, Q3	-7.0, 12.0	0, 7.0
		Min, Max	-20, 13	-13, 20
Week 181	Actual	n	9	8
		Mean (std)	14.1 (14.98)	3.4 (7.15)
		Median	7.0	0
		Q1, Q3	0, 20.0	0, 3.5
		Min, Max	0, 40	0, 20
	Change from BL	n	9	7
		Mean (std)	3.0 (18.84)	-0.9 (4.63)
		Median	6.0	0
		Q1, Q3	-13.0, 7.0	-6.0, 0
		Min, Max	-20, 40	-7, 7

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	26.4 (16.96)	0 (0)
		Median	20.0	0
		Q1, Q3	13.0, 33.0	0, 0
		Min, Max	13, 53	0, 0
	Change from BL	n	5	2
		Mean (std)	9.2 (13.70)	0 (0)
		Median	7.0	0
		Q1, Q3	0, 20.0	0, 0
		Min, Max	-7, 26	0, 0
Week 193	Actual	n	1	0
		Mean (std)	0	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	0	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		-7.0
		Median		-7.0
		Q1, Q3		-7.0, -7.0
		Min, Max		-7, -7
Week 205	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	2.7 (5.73)	2.5 (5.30)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 27	0, 27
	Change from BL	n	181	171
		Mean (std)	-9.9 (12.58)	-9.3 (12.00)
		Median	-7.0	-7.0
		Q1, Q3	-20.0, 0	-13.0, 0
		Min, Max	-53, 20	-67, 13
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	27.3 (19.80)	24.5 (15.38)
		Median	27.0	20.0
		Q1, Q3	13.0, 33.0	13.0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	171
		Mean (std)	14.7 (18.41)	12.5 (15.70)
		Median	13.0	13.0
		Q1, Q3	0, 26.0	6.0, 20.0
		Min, Max	-20, 87	-40, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	183	175
		Mean (std)	14.5 (23.08)	11.8 (19.45)
		Median	0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	177	174
		Mean (std)	29.6 (29.88)	23.8 (27.24)
		Median	33.0	17.0
		Q1, Q3	0, 50.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	173	170
		Mean (std)	17.1 (27.90)	11.5 (24.15)
		Median	16.0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	-50, 100	-34, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	170	166
		Mean (std)	29.7 (29.79)	25.7 (28.86)
		Median	33.0	17.0
		Q1, Q3	0, 50.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	167	162
		Mean (std)	17.2 (26.95)	13.5 (26.86)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-34, 100	-50, 100
Week 10	Actual	n	166	156
		Mean (std)	26.2 (29.38)	25.3 (27.33)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	162	152
		Mean (std)	13.3 (28.30)	12.9 (27.41)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-50, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	157	148
		Mean (std)	30.6 (32.03)	23.9 (27.45)
		Median	33.0	17.0
		Q1, Q3	0, 50.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	153	144
		Mean (std)	18.1 (28.89)	12.3 (29.36)
		Median	16.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-67, 100
Week 16	Actual	n	153	151
		Mean (std)	29.0 (29.80)	24.4 (28.53)
		Median	33.0	17.0
		Q1, Q3	0, 50.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	148	147
		Mean (std)	16.8 (27.41)	12.5 (27.11)
		Median	16.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-50, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	154	149
		Mean (std)	30.9 (33.74)	26.5 (31.18)
		Median	21.0	17.0
		Q1, Q3	0, 50.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	149	145
		Mean (std)	17.9 (29.46)	14.3 (30.45)
		Median	8.5	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-50, 100
Week 25	Actual	n	138	133
		Mean (std)	27.2 (30.41)	23.0 (27.93)
		Median	25.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	135	128
		Mean (std)	13.4 (28.54)	11.0 (26.78)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	128	132
		Mean (std)	24.6 (28.56)	22.5 (27.70)
		Median	17.0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	125	129
		Mean (std)	10.5 (27.44)	9.7 (27.62)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-50, 100
Week 37	Actual	n	114	108
		Mean (std)	22.5 (30.75)	18.9 (25.08)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	111	106
		Mean (std)	10.5 (26.32)	6.9 (25.48)
		Median	0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	-34, 100	-67, 83

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	106	105
		Mean (std)	22.0 (27.01)	17.2 (25.15)
		Median	17.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	104	102
		Mean (std)	10.5 (26.10)	6.6 (27.24)
		Median	0	0
		Q1, Q3	0, 25.0	0, 17.0
		Min, Max	-50, 100	-67, 100
Week 49	Actual	n	94	81
		Mean (std)	18.6 (24.77)	14.8 (22.79)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	91	80
		Mean (std)	7.7 (25.73)	2.7 (22.22)
		Median	0	0
		Q1, Q3	0, 17.0	0, 16.0
		Min, Max	-34, 100	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	90	81
		Mean (std)	18.9 (25.72)	19.5 (26.57)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	87	79
		Mean (std)	7.3 (28.93)	7.1 (24.40)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-50, 100	-67, 67
Week 61	Actual	n	81	65
		Mean (std)	16.1 (22.36)	12.8 (20.52)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	78	64
		Mean (std)	6.1 (24.41)	0.7 (23.23)
		Median	0	0
		Q1, Q3	0, 17.0	0, 0
		Min, Max	-50, 100	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	19.5 (25.75)	15.2 (23.32)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	80	72
		Mean (std)	8.1 (25.00)	3.9 (24.12)
		Median	0	0
		Q1, Q3	0, 17.0	0, 16.0
		Min, Max	-50, 100	-67, 67
Week 73	Actual	n	75	61
		Mean (std)	18.4 (24.28)	18.8 (23.65)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	73	61
		Mean (std)	9.4 (24.33)	6.2 (22.31)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	-33, 100	-50, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	66	57
		Mean (std)	18.9 (26.61)	20.5 (26.34)
		Median	0	17.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	64	55
		Mean (std)	6.8 (26.82)	8.5 (24.97)
		Median	0	0
		Q1, Q3	0, 16.5	0, 17.0
		Min, Max	-50, 100	-67, 83
Week 85	Actual	n	70	58
		Mean (std)	15.1 (24.04)	16.9 (26.56)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	68	58
		Mean (std)	3.8 (25.06)	3.4 (29.06)
		Median	0	0
		Q1, Q3	0, 16.0	0, 17.0
		Min, Max	-50, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	56	47
		Mean (std)	15.4 (23.30)	16.7 (27.15)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	54	47
		Mean (std)	5.8 (26.55)	4.3 (22.12)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 100	-33, 67
Week 97	Actual	n	65	53
		Mean (std)	15.2 (21.66)	16.3 (24.98)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	63	52
		Mean (std)	1.7 (22.86)	4.2 (27.32)
		Median	0	0
		Q1, Q3	-16.0, 17.0	0, 16.0
		Min, Max	-34, 50	-50, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	21.2 (30.66)	12.5 (22.17)
		Median	0	0
		Q1, Q3	0, 33.0	0, 25.0
		Min, Max	0, 100	0, 100
	Change from BL	n	54	42
		Mean (std)	8.6 (31.83)	-0.8 (19.75)
		Median	0	0
		Q1, Q3	0, 17.0	0, 0
		Min, Max	-50, 100	-50, 67
Week 109	Actual	n	52	50
		Mean (std)	17.3 (24.42)	17.3 (25.38)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	51	50
		Mean (std)	1.9 (23.44)	4.6 (20.40)
		Median	0	0
		Q1, Q3	0, 0	0, 16.0
		Min, Max	-67, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	42
		Mean (std)	17.3 (24.03)	17.8 (27.85)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	49	40
		Mean (std)	6.8 (25.90)	2.1 (27.46)
		Median	0	0
		Q1, Q3	0, 16.0	0, 16.0
		Min, Max	-34, 100	-67, 67
Week 121	Actual	n	51	49
		Mean (std)	12.4 (16.85)	11.2 (18.68)
		Median	0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 67	0, 100
	Change from BL	n	50	49
		Mean (std)	-1.0 (17.60)	-1.4 (18.80)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 34	-67, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	40
		Mean (std)	18.1 (27.67)	17.5 (25.59)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	44	39
		Mean (std)	6.8 (28.36)	4.3 (24.27)
		Median	0	0
		Q1, Q3	0, 16.0	0, 17.0
		Min, Max	-34, 100	-33, 67
Week 133	Actual	n	48	43
		Mean (std)	19.0 (27.68)	10.8 (21.13)
		Median	0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	46	43
		Mean (std)	5.8 (27.71)	-1.2 (18.98)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-50, 100	-67, 50

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	35
		Mean (std)	14.5 (24.20)	16.1 (25.34)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	45	35
		Mean (std)	3.3 (27.65)	2.4 (21.42)
		Median	0	0
		Q1, Q3	0, 16.0	0, 16.0
		Min, Max	-34, 100	-67, 67
Week 145	Actual	n	38	30
		Mean (std)	16.6 (26.54)	9.2 (20.54)
		Median	0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	37	30
		Mean (std)	5.8 (26.72)	-1.9 (11.90)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 100	-33, 25

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	16.2 (24.70)	16.6 (25.97)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	35	24
		Mean (std)	0.9 (28.28)	4.1 (18.42)
		Median	0	0
		Q1, Q3	-17.0, 0	0, 16.0
		Min, Max	-34, 100	-33, 50
Week 157	Actual	n	26	20
		Mean (std)	12.2 (24.73)	12.9 (23.91)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	26	20
		Mean (std)	5.1 (30.04)	3.8 (16.68)
		Median	0	0
		Q1, Q3	0, 16.0	0, 17.0
		Min, Max	-33, 100	-33, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	17.5 (32.27)	12.7 (25.99)
		Median	0	0
		Q1, Q3	0, 17.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	21	17
		Mean (std)	5.6 (29.43)	0 (14.29)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 83	-33, 33
Week 169	Actual	n	17	11
		Mean (std)	18.6 (30.54)	13.6 (30.55)
		Median	0	0
		Q1, Q3	0, 33.0	0, 17.0
		Min, Max	0, 100	0, 100
	Change from BL	n	17	11
		Mean (std)	5.9 (27.57)	4.5 (13.15)
		Median	0	0
		Q1, Q3	0, 16.0	0, 17.0
		Min, Max	-33, 84	-17, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	4.2 (10.31)	4.5 (10.73)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 33	0, 33
	Change from BL	n	12	11
		Mean (std)	-5.5 (14.75)	3.0 (12.52)
		Median	0	0
		Q1, Q3	-8.5, 0	0, 0
		Min, Max	-33, 17	-17, 33
Week 181	Actual	n	9	8
		Mean (std)	9.2 (14.58)	4.1 (11.67)
		Median	0	0
		Q1, Q3	0, 17.0	0, 0
		Min, Max	0, 33	0, 33
	Change from BL	n	9	8
		Mean (std)	-0.1 (20.31)	0 (0)
		Median	0	0
		Q1, Q3	-17.0, 16.0	0, 0
		Min, Max	-33, 33	0, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	26.6 (43.45)	0 (0)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 0
	Change from BL	n	5	2
		Mean (std)	6.6 (25.35)	0 (0)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-17, 50	0, 0
Week 193	Actual	n	1	0
		Mean (std)	0	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	0	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	183	178
		Mean (std)	8.6 (18.11)	7.8 (16.22)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	178	173
		Mean (std)	-4.8 (20.29)	-4.2 (19.79)
		Median	0	0
		Q1, Q3	-16.0, 0	-16.0, 0
		Min, Max	-67, 67	-67, 67
Post-Baseline Maximum	Actual	n	183	178
		Mean (std)	50.9 (33.62)	41.8 (33.70)
		Median	50.0	33.0
		Q1, Q3	33.0, 83.0	17.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	178	173
		Mean (std)	37.2 (31.45)	30.2 (32.02)
		Median	33.0	33.0
		Q1, Q3	17.0, 67.0	0, 50.0
		Min, Max	-34, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	40	47
		Mean (std)	12.8 (25.75)	10.6 (21.79)
		Median	0	0
		Q1, Q3	0, 11.0	0, 11.0
		Min, Max	0, 100	0, 89
Week 4	Actual	n	34	37
		Mean (std)	10.4 (17.99)	12.0 (23.47)
		Median	0	0
		Q1, Q3	0, 11.0	0, 22.0
		Min, Max	0, 67	0, 100
	Change from BL	n	20	24
		Mean (std)	0.6 (14.49)	2.3 (7.42)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-44, 33	0, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	40	37
		Mean (std)	20.2 (33.10)	15.3 (23.47)
		Median	0	0
		Q1, Q3	0, 22.0	0, 33.0
		Min, Max	0, 100	0, 89
	Change from BL	n	20	23
		Mean (std)	18.3 (34.82)	1.9 (13.93)
		Median	5.5	0
		Q1, Q3	0, 16.5	0, 0
		Min, Max	-11, 100	-22, 44
Week 10	Actual	n	38	34
		Mean (std)	19.2 (29.42)	9.4 (17.12)
		Median	5.5	0
		Q1, Q3	0, 33.0	0, 11.0
		Min, Max	0, 100	0, 67
	Change from BL	n	17	20
		Mean (std)	13.6 (38.82)	1.1 (10.03)
		Median	11.0	0
		Q1, Q3	0, 22.0	0, 0
		Min, Max	-67, 100	-11, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	30	39
		Mean (std)	14.8 (21.74)	9.5 (17.32)
		Median	0	0
		Q1, Q3	0, 22.0	0, 11.0
		Min, Max	0, 78	0, 67
	Change from BL	n	15	23
		Mean (std)	4.4 (15.44)	3.3 (11.70)
		Median	0	0
		Q1, Q3	0, 11.0	0, 0
		Min, Max	-22, 44	-11, 44
Week 16	Actual	n	32	34
		Mean (std)	12.6 (23.51)	12.7 (19.17)
		Median	0	0
		Q1, Q3	0, 22.0	0, 22.0
		Min, Max	0, 100	0, 78
	Change from BL	n	13	22
		Mean (std)	3.8 (12.97)	3.5 (13.46)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-22, 28	-22, 45

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	32	30
		Mean (std)	12.8 (20.36)	12.9 (22.79)
		Median	0	0
		Q1, Q3	0, 22.0	0, 22.0
		Min, Max	0, 78	0, 100
	Change from BL	n	16	16
		Mean (std)	8.3 (20.90)	-1.4 (13.84)
		Median	0	0
		Q1, Q3	0, 11.0	0, 0
		Min, Max	-11, 78	-33, 33
Week 25	Actual	n	35	29
		Mean (std)	18.9 (28.04)	17.6 (24.95)
		Median	11.0	11.0
		Q1, Q3	0, 33.0	0, 22.0
		Min, Max	0, 100	0, 100
	Change from BL	n	17	15
		Mean (std)	6.5 (24.90)	10.4 (22.51)
		Median	0	0
		Q1, Q3	0, 11.0	0, 22.0
		Min, Max	-23, 89	-11, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	42	30
		Mean (std)	22.4 (25.29)	17.7 (25.01)
		Median	14.0	11.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	20	15
		Mean (std)	9.5 (27.21)	2.9 (14.14)
		Median	0	0
		Q1, Q3	0, 22.5	0, 11.0
		Min, Max	-33, 100	-23, 33
Week 37	Actual	n	32	26
		Mean (std)	19.3 (24.25)	17.4 (21.75)
		Median	11.0	11.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	14	11
		Mean (std)	-0.9 (18.26)	10.0 (18.70)
		Median	0	0
		Q1, Q3	-11.0, 11.0	0, 22.0
		Min, Max	-34, 33	-11, 44

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	39	23
		Mean (std)	20.2 (24.22)	14.4 (18.75)
		Median	11.0	11.0
		Q1, Q3	0, 33.0	0, 22.0
		Min, Max	0, 100	0, 78
	Change from BL	n	18	9
		Mean (std)	4.6 (25.89)	8.6 (16.30)
		Median	0	0
		Q1, Q3	-11.0, 11.0	0, 22.0
		Min, Max	-34, 89	-11, 33
Week 49	Actual	n	23	22
		Mean (std)	15.9 (24.66)	15.6 (25.65)
		Median	11.0	11.0
		Q1, Q3	0, 22.0	0, 11.0
		Min, Max	0, 89	0, 89
	Change from BL	n	11	8
		Mean (std)	8.1 (28.15)	2.8 (12.81)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-11, 89	-11, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	23	15
		Mean (std)	21.2 (22.77)	16.9 (16.73)
		Median	11.0	11.0
		Q1, Q3	0, 22.0	0, 33.0
		Min, Max	0, 78	0, 56
	Change from BL	n	11	6
		Mean (std)	10.1 (24.60)	9.2 (18.95)
		Median	0	0
		Q1, Q3	0, 11.0	0, 33.0
		Min, Max	-11, 78	-11, 33
Week 61	Actual	n	19	15
		Mean (std)	17.8 (27.12)	13.3 (20.64)
		Median	0	0
		Q1, Q3	0, 33.0	0, 22.0
		Min, Max	0, 100	0, 67
	Change from BL	n	8	6
		Mean (std)	10.4 (26.99)	1.8 (17.62)
		Median	0	0
		Q1, Q3	-8.3, 22.0	0, 0
		Min, Max	-11, 67	-22, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	21	17
		Mean (std)	26.9 (32.54)	18.9 (28.24)
		Median	11.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	6	5
		Mean (std)	16.7 (36.38)	8.8 (19.68)
		Median	5.5	0
		Q1, Q3	0, 11.0	0, 0
		Min, Max	-11, 89	0, 44
Week 73	Actual	n	21	15
		Mean (std)	23.1 (28.51)	19.9 (32.32)
		Median	11.0	0
		Q1, Q3	0, 33.0	0, 22.0
		Min, Max	0, 100	0, 100
	Change from BL	n	7	3
		Mean (std)	3.1 (15.18)	11.3 (40.22)
		Median	0	0
		Q1, Q3	-11.0, 11.0	-22.0, 56.0
		Min, Max	-11, 33	-22, 56

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	17	10
		Mean (std)	27.4 (32.69)	25.4 (30.97)
		Median	11.0	22.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	6	3
		Mean (std)	20.3 (41.20)	11.0 (19.05)
		Median	11.0	0
		Q1, Q3	-11.0, 22.0	0, 33.0
		Min, Max	-11, 100	0, 33
Week 85	Actual	n	21	11
		Mean (std)	20.6 (28.18)	17.1 (29.53)
		Median	0	11.0
		Q1, Q3	0, 33.0	0, 22.0
		Min, Max	0, 100	0, 100
	Change from BL	n	4	5
		Mean (std)	5.8 (11.50)	-4.4 (9.84)
		Median	0	0
		Q1, Q3	0, 11.5	0, 0
		Min, Max	0, 23	-22, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	17	10
		Mean (std)	21.5 (27.98)	30.0 (38.22)
		Median	11.0	16.5
		Q1, Q3	0, 33.0	0, 56.0
		Min, Max	0, 89	0, 100
	Change from BL	n	4	2
		Mean (std)	30.5 (40.02)	0 (0)
		Median	16.5	0
		Q1, Q3	5.5, 55.5	0, 0
		Min, Max	0, 89	0, 0
Week 97	Actual	n	17	12
		Mean (std)	20.8 (25.95)	25.8 (28.99)
		Median	22.0	16.5
		Q1, Q3	0, 33.0	0, 38.5
		Min, Max	0, 100	0, 89
	Change from BL	n	6	3
		Mean (std)	-13.0 (44.07)	-7.3 (12.70)
		Median	0	0
		Q1, Q3	-11.0, 11.0	-22.0, 0
		Min, Max	-100, 22	-22, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	14	9
		Mean (std)	27.0 (34.30)	19.8 (25.48)
		Median	5.5	11.0
		Q1, Q3	0, 56.0	0, 22.0
		Min, Max	0, 100	0, 67
	Change from BL	n	6	2
		Mean (std)	11.2 (26.29)	0 (0)
		Median	0	0
		Q1, Q3	-11.0, 44.0	0, 0
		Min, Max	-11, 45	0, 0
Week 109	Actual	n	10	12
		Mean (std)	21.0 (21.27)	28.6 (30.89)
		Median	22.0	22.0
		Q1, Q3	0, 22.0	0, 44.0
		Min, Max	0, 67	0, 89
	Change from BL	n	1	4
		Mean (std)	-11.0	-5.8 (11.50)
		Median	-11.0	0
		Q1, Q3	-11.0, -11.0	-11.5, 0
		Min, Max	-11, -11	-23, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	11	7
		Mean (std)	15.1 (30.31)	15.9 (25.62)
		Median	0	0
		Q1, Q3	0, 22.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	4	2
		Mean (std)	-5.5 (6.35)	-11.0 (15.56)
		Median	-5.5	-11.0
		Q1, Q3	-11.0, 0	-22.0, 0
		Min, Max	-11, 0	-22, 0
Week 121	Actual	n	12	13
		Mean (std)	33.3 (34.24)	20.6 (30.88)
		Median	22.0	0
		Q1, Q3	5.5, 50.0	0, 56.0
		Min, Max	0, 100	0, 78
	Change from BL	n	3	4
		Mean (std)	29.7 (51.38)	-2.8 (5.50)
		Median	0	0
		Q1, Q3	0, 89.0	-5.5, 0
		Min, Max	0, 89	-11, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	15	10
		Mean (std)	16.2 (26.15)	26.6 (40.30)
		Median	11.0	5.5
		Q1, Q3	0, 22.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	4	3
		Mean (std)	-2.8 (5.50)	11.0 (19.05)
		Median	0	0
		Q1, Q3	-5.5, 0	0, 33.0
		Min, Max	-11, 0	0, 33
Week 133	Actual	n	17	10
		Mean (std)	28.8 (27.67)	24.5 (33.58)
		Median	22.0	5.5
		Q1, Q3	11.0, 56.0	0, 56.0
		Min, Max	0, 78	0, 89
	Change from BL	n	5	2
		Mean (std)	15.6 (34.88)	-5.5 (7.78)
		Median	0	-5.5
		Q1, Q3	0, 0	-11.0, 0
		Min, Max	0, 78	-11, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	12	11
		Mean (std)	13.8 (29.97)	26.3 (35.66)
		Median	0	11.0
		Q1, Q3	0, 16.5	0, 56.0
		Min, Max	0, 100	0, 100
	Change from BL	n	5	1
		Mean (std)	0 (0)	0
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 0	0, 0
Week 145	Actual	n	12	9
		Mean (std)	28.6 (34.64)	22.1 (32.37)
		Median	22.0	11.0
		Q1, Q3	0, 38.5	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	4	2
		Mean (std)	22.3 (44.50)	-5.5 (7.78)
		Median	0	-5.5
		Q1, Q3	0, 44.5	-11.0, 0
		Min, Max	0, 89	-11, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	10	6
		Mean (std)	17.6 (13.91)	20.3 (34.77)
		Median	22.0	5.5
		Q1, Q3	0, 33.0	0, 22.0
		Min, Max	0, 33	0, 89
	Change from BL	n	4	1
		Mean (std)	2.8 (5.50)	0
		Median	0	0
		Q1, Q3	0, 5.5	0, 0
		Min, Max	0, 11	0, 0
Week 157	Actual	n	7	6
		Mean (std)	19.0 (31.94)	37.0 (36.38)
		Median	11.0	27.5
		Q1, Q3	0, 22.0	11.0, 56.0
		Min, Max	0, 89	0, 100
	Change from BL	n	4	0
		Mean (std)	22.3 (45.40)	
		Median	5.5	
		Q1, Q3	-5.5, 50.0	
		Min, Max	-11, 89	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	4	5
		Mean (std)	36.3 (30.84)	22.2 (32.50)
		Median	39.0	11.0
		Q1, Q3	11.0, 61.5	0, 22.0
		Min, Max	0, 67	0, 78
	Change from BL	n	1	1
		Mean (std)	67.0	-11.0
		Median	67.0	-11.0
		Q1, Q3	67.0, 67.0	-11.0, -11.0
		Min, Max	67, 67	-11, -11
Week 169	Actual	n	7	4
		Mean (std)	30.0 (31.24)	27.8 (48.44)
		Median	33.0	5.5
		Q1, Q3	0, 44.0	0, 55.5
		Min, Max	0, 89	0, 100
	Change from BL	n	3	0
		Mean (std)	18.7 (32.33)	
		Median	0	
		Q1, Q3	0, 56.0	
		Min, Max	0, 56	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	4	5
		Mean (std)	11.0 (12.70)	11.0 (13.47)
		Median	11.0	11.0
		Q1, Q3	0, 22.0	0, 11.0
		Min, Max	0, 22	0, 33
	Change from BL	n	2	1
		Mean (std)	11.0 (15.56)	-11.0
		Median	11.0	-11.0
		Q1, Q3	0, 22.0	-11.0, -11.0
		Min, Max	0, 22	-11, -11
Week 181	Actual	n	3	3
		Mean (std)	14.7 (25.40)	11.0 (11.00)
		Median	0	11.0
		Q1, Q3	0, 44.0	0, 22.0
		Min, Max	0, 44	0, 22
	Change from BL	n	1	0
		Mean (std)	11.0	
		Median	11.0	
		Q1, Q3	11.0, 11.0	
		Min, Max	11, 11	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	4	1
		Mean (std)	36.0 (37.90)	22.0
		Median	27.5	22.0
		Q1, Q3	11.0, 61.0	22.0, 22.0
		Min, Max	0, 89	22, 22
	Change from BL	n	2	0
		Mean (std)	44.5 (62.93)	
		Median	44.5	
		Q1, Q3	0, 89.0	
		Min, Max	0, 89	
Post-Baseline Minimum	Actual	n	98	89
		Mean (std)	7.8 (17.95)	7.0 (19.71)
		Median	0	0
		Q1, Q3	0, 11.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	32	36
		Mean (std)	-8.0 (22.84)	-3.1 (12.42)
		Median	0	0
		Q1, Q3	-11.0, 0	0, 0
		Min, Max	-100, 22	-34, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Maximum	Actual	n	98	89
		Mean (std)	29.3 (33.07)	24.2 (31.40)
		Median	19.5	11.0
		Q1, Q3	0, 44.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	32	36
		Mean (std)	21.8 (34.75)	12.0 (20.26)
		Median	11.0	0
		Q1, Q3	0, 38.5	0, 27.5
		Min, Max	-44, 100	-22, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	184	173
		Mean (std)	27.3 (28.03)	25.7 (30.33)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	177	175
		Mean (std)	22.6 (25.78)	19.1 (24.30)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	174	169
		Mean (std)	-4.0 (28.75)	-6.6 (26.58)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-100, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	167
		Mean (std)	20.0 (26.85)	16.3 (23.07)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	168	160
		Mean (std)	-7.0 (28.72)	-9.0 (27.90)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-100, 67
Week 10	Actual	n	168	157
		Mean (std)	16.2 (22.75)	14.0 (23.24)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	164	150
		Mean (std)	-10.3 (28.73)	-8.6 (30.06)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 67	-100, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	149
		Mean (std)	19.9 (25.69)	16.6 (23.61)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	156	142
		Mean (std)	-7.0 (30.78)	-7.4 (30.72)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-100, 67
Week 16	Actual	n	155	150
		Mean (std)	18.1 (23.27)	19.3 (27.39)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	151	144
		Mean (std)	-8.5 (29.98)	-5.5 (30.06)
		Median	0	0
		Q1, Q3	-33.0, 0	-16.5, 0
		Min, Max	-100, 67	-100, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	18.6 (26.59)	17.0 (25.65)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	145
		Mean (std)	-7.8 (34.16)	-7.1 (28.43)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-100, 67
Week 25	Actual	n	140	135
		Mean (std)	23.5 (27.57)	19.5 (28.04)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	137	129
		Mean (std)	-2.2 (30.59)	-3.3 (24.26)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	133
		Mean (std)	21.6 (27.63)	21.6 (29.58)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	126	129
		Mean (std)	-3.9 (33.32)	-1.7 (28.11)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-100, 100	-67, 100
Week 37	Actual	n	115	108
		Mean (std)	19.9 (24.11)	19.7 (23.13)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	112	103
		Mean (std)	-3.8 (29.95)	-1.6 (25.87)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	107	107
		Mean (std)	22.2 (25.80)	18.2 (25.75)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	105	103
		Mean (std)	-3.0 (28.94)	-4.0 (24.62)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-67, 67
Week 49	Actual	n	94	83
		Mean (std)	29.0 (31.51)	23.6 (25.83)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	91	80
		Mean (std)	5.9 (29.98)	0.4 (26.78)
		Median	0	0
		Q1, Q3	0, 33.0	-16.5, 0
		Min, Max	-67, 100	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	91	84
		Mean (std)	24.8 (27.95)	21.3 (25.67)
		Median	33.0	16.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	88	81
		Mean (std)	2.7 (34.77)	-2.5 (25.10)
		Median	0	0
		Q1, Q3	-33.0, 33.0	-33.0, 0
		Min, Max	-100, 100	-67, 67
Week 61	Actual	n	80	66
		Mean (std)	21.0 (26.13)	23.7 (27.94)
		Median	0	16.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	78	63
		Mean (std)	-2.3 (28.95)	3.7 (26.94)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 33.0
		Min, Max	-67, 67	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	28.4 (30.65)	25.5 (30.21)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	80	70
		Mean (std)	3.8 (34.81)	-1.4 (26.94)
		Median	0	0
		Q1, Q3	-33.0, 33.0	-33.0, 0
		Min, Max	-100, 100	-67, 67
Week 73	Actual	n	76	62
		Mean (std)	22.3 (26.91)	17.9 (25.28)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	73	61
		Mean (std)	-2.3 (32.10)	-3.0 (20.06)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-67, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	23.8 (26.46)	19.5 (29.97)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	64	56
		Mean (std)	-2.1 (33.56)	-1.8 (29.46)
		Median	0	0
		Q1, Q3	-33.0, 16.5	-16.5, 0
		Min, Max	-100, 67	-67, 100
Week 85	Actual	n	70	58
		Mean (std)	25.1 (28.63)	23.5 (29.32)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	68	58
		Mean (std)	-2.5 (36.19)	-1.1 (27.22)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 100	-34, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	56	48
		Mean (std)	19.0 (28.32)	17.6 (25.12)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	54	48
		Mean (std)	-5.5 (36.51)	-4.5 (31.38)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 100	-67, 67
Week 97	Actual	n	65	53
		Mean (std)	23.8 (28.57)	20.7 (25.57)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	62	52
		Mean (std)	-4.6 (32.28)	-1.3 (25.59)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 67	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	26.2 (25.20)	22.7 (27.68)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	54	42
		Mean (std)	1.5 (34.68)	-2.3 (23.91)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-84, 100	-67, 34
Week 109	Actual	n	52	51
		Mean (std)	22.3 (26.16)	18.2 (28.52)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	51	51
		Mean (std)	-8.5 (33.92)	-3.9 (26.38)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 67	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	50	43
		Mean (std)	18.0 (26.29)	23.1 (26.75)
		Median	0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	49	41
		Mean (std)	-4.7 (26.41)	-0.9 (26.39)
		Median	0	0
		Q1, Q3	0, 0	-33.0, 0
		Min, Max	-67, 34	-34, 67
Week 121	Actual	n	50	50
		Mean (std)	24.6 (32.19)	21.3 (29.17)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	50	49
		Mean (std)	-4.0 (37.29)	-1.3 (28.84)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 100	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	44	41
		Mean (std)	19.6 (26.20)	19.5 (27.91)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	44	41
		Mean (std)	-6.9 (34.23)	-6.5 (31.05)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 100	-67, 67
Week 133	Actual	n	48	43
		Mean (std)	24.9 (24.36)	17.0 (24.51)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	46	42
		Mean (std)	-4.3 (30.40)	-7.2 (27.06)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 67	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	45	36
		Mean (std)	21.4 (26.77)	30.6 (33.31)
		Median	0	33.0
		Q1, Q3	0, 33.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	45	36
		Mean (std)	-5.9 (29.63)	3.8 (29.74)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 33.5
		Min, Max	-67, 67	-67, 67
Week 145	Actual	n	38	31
		Mean (std)	21.9 (29.35)	16.1 (25.62)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	37	30
		Mean (std)	-2.6 (33.65)	-5.6 (23.35)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-67, 34

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	25
		Mean (std)	21.2 (26.62)	28.0 (35.62)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	35	25
		Mean (std)	-10.5 (33.21)	0 (27.30)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 100	-67, 67
Week 157	Actual	n	26	20
		Mean (std)	22.1 (25.11)	21.7 (29.29)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 50.3
		Min, Max	0, 100	0, 67
	Change from BL	n	26	19
		Mean (std)	-2.1 (30.71)	1.9 (26.12)
		Median	0	0
		Q1, Q3	-22.3, 0	0, 0
		Min, Max	-67, 100	-34, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	16.6 (22.36)	23.5 (28.39)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	21	17
		Mean (std)	-11.9 (27.48)	-1.9 (27.67)
		Median	0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-67, 34	-34, 67
Week 169	Actual	n	17	11
		Mean (std)	17.6 (26.74)	24.3 (36.86)
		Median	0	0
		Q1, Q3	0, 33.0	0, 67.0
		Min, Max	0, 67	0, 100
	Change from BL	n	17	10
		Mean (std)	-19.6 (33.57)	6.7 (30.54)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 33.0
		Min, Max	-67, 34	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	25.0 (28.97)	12.1 (22.49)
		Median	16.5	0
		Q1, Q3	0, 50.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	12	11
		Mean (std)	-8.3 (38.12)	-3.0 (40.70)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-67, 67	-100, 67
Week 181	Actual	n	9	8
		Mean (std)	25.8 (32.36)	4.1 (11.67)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 33
	Change from BL	n	9	7
		Mean (std)	-11.3 (50.08)	-4.7 (12.47)
		Median	-33.0	0
		Q1, Q3	-34.0, 0	0, 0
		Min, Max	-67, 100	-33, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	39.8 (36.56)	33.5 (47.38)
		Median	33.0	33.5
		Q1, Q3	33.0, 33.0	0, 67.0
		Min, Max	0, 100	0, 67
	Change from BL	n	5	2
		Mean (std)	-0.2 (62.54)	33.5 (47.38)
		Median	0	33.5
		Q1, Q3	-34.0, 0	0, 67.0
		Min, Max	-67, 100	0, 67
Week 193	Actual	n	1	0
		Mean (std)	0	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	-33.0	
		Median	-33.0	
		Q1, Q3	-33.0, -33.0	
		Min, Max	-33, -33	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		33.0
		Median		33.0
		Q1, Q3		33.0, 33.0
		Min, Max		33, 33
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	5.8 (15.63)	5.4 (15.47)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	180	171
		Mean (std)	-21.2 (27.46)	-20.0 (27.90)
		Median	-33.0	0
		Q1, Q3	-33.0, 0	-33.0, 0
		Min, Max	-100, 34	-100, 34
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	52.3 (31.21)	46.4 (32.82)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	180	171
		Mean (std)	24.8 (33.16)	21.1 (30.51)
		Median	33.0	33.0
		Q1, Q3	0, 34.0	0, 34.0
		Min, Max	-100, 100	-100, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	174
		Mean (std)	15.4 (26.86)	12.2 (22.41)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	179	176
		Mean (std)	31.6 (32.45)	25.9 (27.68)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	177	170
		Mean (std)	16.7 (32.31)	12.7 (27.14)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	167
		Mean (std)	39.5 (32.92)	32.2 (27.55)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	169	161
		Mean (std)	23.8 (33.99)	19.4 (32.64)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-100, 100
Week 10	Actual	n	167	157
		Mean (std)	44.3 (32.91)	36.0 (28.59)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	164	151
		Mean (std)	31.3 (35.43)	23.8 (29.94)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	-67, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	159	150
		Mean (std)	48.6 (32.32)	42.3 (31.64)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	156	144
		Mean (std)	33.6 (39.89)	29.1 (36.28)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	-67, 100	-100, 100
Week 16	Actual	n	155	151
		Mean (std)	54.7 (33.37)	50.8 (34.27)
		Median	67.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	145
		Mean (std)	40.5 (41.15)	36.8 (37.06)
		Median	33.5	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	-67, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	59.1 (31.52)	50.2 (33.22)
		Median	67.0	33.0
		Q1, Q3	33.0, 83.5	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	153	146
		Mean (std)	44.8 (39.68)	37.0 (38.44)
		Median	34.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	-67, 100	-100, 100
Week 25	Actual	n	140	135
		Mean (std)	54.2 (32.66)	46.2 (33.62)
		Median	67.0	33.0
		Q1, Q3	33.0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	138	130
		Mean (std)	41.7 (39.71)	35.0 (36.97)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	-67, 100	-100, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	128	133
		Mean (std)	50.0 (32.45)	40.2 (34.96)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	126	129
		Mean (std)	36.0 (39.95)	28.3 (36.99)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	-84, 100	-100, 100
Week 37	Actual	n	115	108
		Mean (std)	45.9 (32.82)	38.7 (32.69)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	113	105
		Mean (std)	32.6 (38.94)	29.7 (37.15)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	-100, 100	-100, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	107	107
		Mean (std)	43.6 (32.61)	35.8 (33.33)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	106	104
		Mean (std)	29.9 (36.86)	26.3 (35.01)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	-100, 100	-100, 100
Week 49	Actual	n	94	83
		Mean (std)	46.2 (31.05)	35.3 (32.32)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	92	81
		Mean (std)	30.3 (38.76)	25.5 (35.50)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 34.0
		Min, Max	-100, 100	-100, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	92	84
		Mean (std)	37.6 (32.94)	35.7 (33.92)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	90	82
		Mean (std)	23.3 (38.24)	27.3 (36.75)
		Median	33.0	33.0
		Q1, Q3	0, 34.0	0, 67.0
		Min, Max	-100, 100	-100, 100
Week 61	Actual	n	81	66
		Mean (std)	47.3 (32.54)	31.3 (30.42)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	79	64
		Mean (std)	31.6 (38.16)	22.0 (33.78)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 34.0
		Min, Max	-100, 100	-100, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	43.4 (32.26)	37.9 (35.36)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	80	71
		Mean (std)	28.8 (42.10)	26.8 (40.15)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	-100, 100	-100, 100
Week 73	Actual	n	76	61
		Mean (std)	40.3 (32.43)	29.4 (30.54)
		Median	33.0	33.0
		Q1, Q3	16.5, 67.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	74	60
		Mean (std)	25.7 (37.34)	21.1 (33.62)
		Median	33.0	16.5
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	-100, 100	-100, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	66	58
		Mean (std)	40.9 (32.02)	31.5 (30.28)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	64	56
		Mean (std)	25.6 (41.10)	23.8 (34.10)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	-100, 100	-100, 100
Week 85	Actual	n	70	57
		Mean (std)	38.7 (31.78)	32.1 (32.18)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	68	57
		Mean (std)	22.3 (35.75)	23.4 (30.24)
		Median	33.0	33.0
		Q1, Q3	0, 33.5	0, 34.0
		Min, Max	-100, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	56	48
		Mean (std)	30.9 (27.68)	33.3 (34.43)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	54	48
		Mean (std)	19.1 (37.55)	25.7 (37.20)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.5
		Min, Max	-100, 100	-100, 100
Week 97	Actual	n	65	53
		Mean (std)	43.3 (31.95)	33.9 (32.44)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	63	52
		Mean (std)	26.7 (40.62)	25.7 (30.04)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 34.0
		Min, Max	-100, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	38.4 (27.67)	36.3 (32.87)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	54	42
		Mean (std)	23.1 (35.01)	30.1 (32.79)
		Median	33.0	33.0
		Q1, Q3	0, 34.0	0, 67.0
		Min, Max	-100, 100	-33, 100
Week 109	Actual	n	52	51
		Mean (std)	37.1 (29.36)	33.3 (31.34)
		Median	33.0	33.0
		Q1, Q3	16.5, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	51	51
		Mean (std)	22.2 (39.31)	26.8 (34.01)
		Median	33.0	33.0
		Q1, Q3	0, 34.0	0, 34.0
		Min, Max	-100, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	38.5 (28.70)	36.4 (33.26)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	49	41
		Mean (std)	23.1 (36.84)	29.3 (31.86)
		Median	33.0	33.0
		Q1, Q3	0, 34.0	0, 67.0
		Min, Max	-100, 100	-33, 100
Week 121	Actual	n	50	50
		Mean (std)	39.9 (30.22)	35.3 (32.66)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	49	50
		Mean (std)	24.5 (44.54)	31.3 (33.99)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	-100, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	41
		Mean (std)	42.2 (30.60)	31.6 (28.89)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	44	41
		Mean (std)	27.3 (37.63)	23.6 (30.04)
		Median	33.0	33.0
		Q1, Q3	0, 50.5	0, 33.0
		Min, Max	-100, 100	-33, 100
Week 133	Actual	n	48	43
		Mean (std)	37.4 (29.75)	37.9 (30.59)
		Median	33.0	33.0
		Q1, Q3	33.0, 50.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	46	42
		Mean (std)	23.1 (39.06)	33.3 (33.76)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 67.0
		Min, Max	-100, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	45	36
		Mean (std)	39.9 (31.54)	36.1 (35.13)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	44	36
		Mean (std)	21.9 (38.04)	29.6 (36.35)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 67.0
		Min, Max	-100, 100	-33, 100
Week 145	Actual	n	37	31
		Mean (std)	39.6 (28.28)	34.4 (32.83)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	36	30
		Mean (std)	25.9 (40.01)	30.0 (32.05)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	-100, 100	0, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	25
		Mean (std)	45.3 (29.03)	33.3 (31.99)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	35	25
		Mean (std)	29.5 (25.33)	30.6 (30.40)
		Median	33.0	33.0
		Q1, Q3	0, 34.0	0, 67.0
		Min, Max	0, 100	0, 100
Week 157	Actual	n	26	20
		Mean (std)	45.7 (31.28)	35.0 (31.60)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	26	19
		Mean (std)	36.8 (33.32)	29.9 (27.10)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	34.0 (26.14)	19.5 (23.75)
		Median	33.0	0
		Q1, Q3	33.0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	21	17
		Mean (std)	23.0 (30.00)	15.6 (26.63)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-33, 100	-33, 67
Week 169	Actual	n	17	11
		Mean (std)	52.8 (31.46)	33.4 (36.61)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	17	10
		Mean (std)	39.2 (29.56)	33.4 (38.59)
		Median	33.0	16.5
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	30.5 (33.26)	24.1 (21.54)
		Median	33.0	33.0
		Q1, Q3	0, 50.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	12	11
		Mean (std)	27.8 (31.28)	24.1 (21.54)
		Median	33.0	33.0
		Q1, Q3	0, 33.5	0, 33.0
		Min, Max	0, 100	0, 67
Week 181	Actual	n	9	8
		Mean (std)	51.8 (33.92)	20.6 (17.08)
		Median	33.0	33.0
		Q1, Q3	33.0, 67.0	0, 33.0
		Min, Max	0, 100	0, 33
	Change from BL	n	9	7
		Mean (std)	33.3 (37.34)	14.1 (17.64)
		Median	33.0	0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	66.8 (40.83)	0 (0)
		Median	67.0	0
		Q1, Q3	67.0, 100.0	0, 0
		Min, Max	0, 100	0, 0
	Change from BL	n	5	2
		Mean (std)	40.2 (43.49)	0 (0)
		Median	34.0	0
		Q1, Q3	0, 67.0	0, 0
		Min, Max	0, 100	0, 0
Week 193	Actual	n	1	0
		Mean (std)	33.0	
		Median	33.0	
		Q1, Q3	33.0, 33.0	
		Min, Max	33, 33	
	Change from BL	n	1	0
		Mean (std)	33.0	
		Median	33.0	
		Q1, Q3	33.0, 33.0	
		Min, Max	33, 33	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

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Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		33.0
		Median		33.0
		Q1, Q3		33.0, 33.0
		Min, Max		33, 33
	Change from BL	n	0	1
		Mean (std)		33.0
		Median		33.0
		Q1, Q3		33.0, 33.0
		Min, Max		33, 33
Week 205	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	15.3 (23.59)	11.2 (19.65)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	172
		Mean (std)	0.5 (28.84)	-1.4 (23.39)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-100, 100
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	74.5 (29.30)	65.2 (31.55)
		Median	67.0	67.0
		Q1, Q3	67.0, 100.0	33.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	172
		Mean (std)	59.6 (37.41)	52.2 (35.58)
		Median	67.0	67.0
		Q1, Q3	33.0, 100.0	33.0, 67.0
		Min, Max	-33, 100	-67, 100

n for "Actual" is number of subjects with non-missing values at the analysis timepoint. n for "Change from BL" is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	174
		Mean (std)	19.1 (26.33)	14.7 (22.46)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	179	176
		Mean (std)	26.6 (28.98)	24.0 (27.60)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	177	170
		Mean (std)	7.2 (29.32)	8.6 (25.92)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	171	167
		Mean (std)	29.2 (29.27)	27.0 (26.82)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	168	161
		Mean (std)	9.8 (29.74)	12.0 (26.73)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-67, 100
Week 10	Actual	n	167	157
		Mean (std)	27.3 (30.05)	27.3 (28.15)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	164	151
		Mean (std)	10.0 (32.67)	14.3 (30.94)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	150
		Mean (std)	31.1 (30.72)	28.3 (25.78)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	157	144
		Mean (std)	11.8 (34.52)	14.1 (28.03)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-67, 100
Week 16	Actual	n	155	151
		Mean (std)	34.5 (31.36)	31.1 (29.81)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	145
		Mean (std)	13.3 (35.50)	15.5 (29.71)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	155	152
		Mean (std)	29.1 (27.38)	26.9 (28.73)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	146
		Mean (std)	10.1 (32.83)	11.2 (30.44)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-67, 100
Week 25	Actual	n	140	135
		Mean (std)	31.2 (29.07)	26.3 (28.79)
		Median	33.0	33.0
		Q1, Q3	0, 41.5	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	138	130
		Mean (std)	13.6 (31.34)	12.1 (26.50)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	133
		Mean (std)	30.2 (30.45)	27.1 (27.20)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	127	129
		Mean (std)	11.0 (34.91)	12.6 (25.74)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-67, 100
Week 37	Actual	n	114	108
		Mean (std)	25.9 (26.90)	25.4 (26.04)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	112	105
		Mean (std)	7.7 (30.70)	13.1 (25.28)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	107	107
		Mean (std)	35.1 (31.98)	23.7 (26.80)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	106	104
		Mean (std)	14.8 (30.34)	11.4 (24.80)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-34, 100
Week 49	Actual	n	94	83
		Mean (std)	34.2 (31.22)	22.8 (23.82)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	92	81
		Mean (std)	14.7 (30.65)	9.0 (24.70)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-34, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	92	82
		Mean (std)	32.1 (28.64)	32.0 (28.02)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	90	80
		Mean (std)	13.3 (28.68)	19.6 (27.96)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-33, 100
Week 61	Actual	n	81	66
		Mean (std)	33.5 (28.77)	23.9 (25.20)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	79	64
		Mean (std)	15.0 (30.10)	11.2 (31.14)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-100, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	33.7 (29.94)	28.2 (29.27)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	80	71
		Mean (std)	14.6 (32.28)	13.6 (29.58)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-34, 100
Week 73	Actual	n	76	62
		Mean (std)	29.1 (29.88)	25.1 (25.39)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	74	61
		Mean (std)	11.5 (36.30)	12.5 (23.61)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	66	58
		Mean (std)	27.2 (29.80)	19.4 (19.71)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	64	56
		Mean (std)	7.3 (28.15)	6.5 (27.19)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-100, 67
Week 85	Actual	n	70	58
		Mean (std)	36.6 (30.19)	25.8 (23.44)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	68	58
		Mean (std)	17.6 (34.85)	13.8 (30.59)
		Median	33.0	16.5
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-100, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	56	48
		Mean (std)	25.5 (26.99)	23.9 (25.06)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	54	48
		Mean (std)	9.2 (30.68)	10.8 (23.89)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-33, 67
Week 97	Actual	n	65	53
		Mean (std)	35.8 (29.13)	23.2 (22.25)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	63	52
		Mean (std)	18.0 (34.85)	12.1 (24.60)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	30.5 (30.78)	28.0 (27.86)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	54	42
		Mean (std)	11.4 (35.49)	16.7 (24.71)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-33, 67
Week 109	Actual	n	52	51
		Mean (std)	33.2 (28.08)	26.6 (24.96)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	51	51
		Mean (std)	15.7 (35.53)	15.6 (20.29)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	24.1 (26.74)	21.7 (25.12)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	49	41
		Mean (std)	4.7 (31.96)	10.6 (27.31)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 67	-34, 67
Week 121	Actual	n	50	50
		Mean (std)	26.6 (27.80)	23.2 (26.29)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	49	50
		Mean (std)	10.2 (33.49)	13.9 (24.33)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 67	-34, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	41
		Mean (std)	28.8 (28.12)	26.7 (26.05)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	44	41
		Mean (std)	11.4 (37.39)	13.8 (24.64)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-34, 100
Week 133	Actual	n	47	43
		Mean (std)	33.3 (29.56)	23.2 (23.64)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	45	42
		Mean (std)	19.2 (34.53)	14.3 (24.51)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	25.2 (24.54)	24.0 (25.97)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	45	36
		Mean (std)	9.6 (36.73)	9.3 (27.03)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-33, 67
Week 145	Actual	n	38	31
		Mean (std)	28.9 (27.10)	20.4 (26.78)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	37	30
		Mean (std)	11.7 (33.60)	11.1 (23.62)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 67	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	25
		Mean (std)	32.3 (25.89)	25.2 (24.16)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	35	25
		Mean (std)	17.1 (29.65)	12.0 (25.15)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-34, 100	-33, 67
Week 157	Actual	n	26	20
		Mean (std)	34.5 (25.88)	25.7 (21.95)
		Median	33.0	33.0
		Q1, Q3	33.0, 33.3	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	26	19
		Mean (std)	23.1 (30.99)	20.1 (25.08)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-34, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	31.6 (26.88)	31.4 (30.12)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 67.0
		Min, Max	0, 100	0, 67
	Change from BL	n	21	17
		Mean (std)	19.0 (28.99)	19.8 (35.50)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 34.0
		Min, Max	-33, 67	-33, 67
Week 169	Actual	n	17	11
		Mean (std)	41.1 (38.29)	39.4 (25.21)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	33.0, 67.0
		Min, Max	0, 100	0, 67
	Change from BL	n	17	10
		Mean (std)	29.4 (37.04)	26.8 (30.67)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 34.0
		Min, Max	-33, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	38.8 (24.11)	21.2 (27.04)
		Median	33.0	0
		Q1, Q3	33.0, 67.0	0, 33.0
		Min, Max	0, 67	0, 67
	Change from BL	n	12	11
		Mean (std)	25.0 (25.09)	9.2 (33.54)
		Median	33.0	0
		Q1, Q3	16.5, 33.5	-33.0, 33.0
		Min, Max	-33, 67	-33, 67
Week 181	Actual	n	9	8
		Mean (std)	40.7 (40.11)	25.0 (29.66)
		Median	33.0	16.5
		Q1, Q3	0, 67.0	0, 50.0
		Min, Max	0, 100	0, 67
	Change from BL	n	9	7
		Mean (std)	22.2 (57.78)	23.9 (31.84)
		Median	0	0
		Q1, Q3	0, 67.0	0, 67.0
		Min, Max	-67, 100	0, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	80.0 (29.91)	33.5 (47.38)
		Median	100.0	33.5
		Q1, Q3	67.0, 100.0	0, 67.0
		Min, Max	33, 100	0, 67
	Change from BL	n	5	2
		Mean (std)	53.4 (38.11)	33.5 (47.38)
		Median	67.0	33.5
		Q1, Q3	33.0, 67.0	0, 67.0
		Min, Max	0, 100	0, 67
Week 193	Actual	n	1	0
		Mean (std)	33.0	
		Median	33.0	
		Q1, Q3	33.0, 33.0	
		Min, Max	33, 33	
	Change from BL	n	1	0
		Mean (std)	33.0	
		Median	33.0	
		Q1, Q3	33.0, 33.0	
		Min, Max	33, 33	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		33.0
		Median		33.0
		Q1, Q3		33.0, 33.0
		Min, Max		33, 33
	Change from BL	n	0	1
		Mean (std)		33.0
		Median		33.0
		Q1, Q3		33.0, 33.0
		Min, Max		33, 33
Week 205	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	7.9 (14.98)	7.3 (16.26)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	181	172
		Mean (std)	-10.9 (24.28)	-7.5 (20.69)
		Median	0	0
		Q1, Q3	-33.0, 0	0, 0
		Min, Max	-100, 33	-100, 34
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	64.5 (30.80)	57.9 (29.84)
		Median	67.0	67.0
		Q1, Q3	33.0, 100.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	172
		Mean (std)	45.4 (33.38)	42.7 (33.16)
		Median	34.0	34.0
		Q1, Q3	33.0, 67.0	33.0, 67.0
		Min, Max	-34, 100	-34, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	185	174
		Mean (std)	4.8 (15.72)	3.6 (14.52)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	178	175
		Mean (std)	85.2 (26.36)	78.5 (27.94)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	175	169
		Mean (std)	81.2 (29.11)	75.4 (30.50)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	-33, 100	0, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	170	167
		Mean (std)	81.2 (32.26)	76.5 (34.22)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	166	161
		Mean (std)	76.3 (35.82)	72.9 (36.00)
		Median	100.0	100.0
		Q1, Q3	67.0, 100.0	67.0, 100.0
		Min, Max	-67, 100	-33, 100
Week 10	Actual	n	167	157
		Mean (std)	74.0 (37.96)	73.4 (38.05)
		Median	100.0	100.0
		Q1, Q3	33.0, 100.0	33.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	163	151
		Mean (std)	70.6 (38.58)	69.4 (38.64)
		Median	100.0	100.0
		Q1, Q3	33.0, 100.0	33.0, 100.0
		Min, Max	0, 100	0, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	157	148
		Mean (std)	72.6 (39.17)	74.2 (39.17)
		Median	100.0	100.0
		Q1, Q3	33.0, 100.0	33.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	153	142
		Mean (std)	68.2 (38.72)	69.6 (40.34)
		Median	100.0	100.0
		Q1, Q3	33.0, 100.0	33.0, 100.0
		Min, Max	0, 100	0, 100
Week 16	Actual	n	154	151
		Mean (std)	71.2 (40.06)	71.1 (41.76)
		Median	100.0	100.0
		Q1, Q3	33.0, 100.0	33.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	150	145
		Mean (std)	66.5 (42.28)	66.9 (42.41)
		Median	100.0	100.0
		Q1, Q3	33.0, 100.0	33.0, 100.0
		Min, Max	-100, 100	0, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	153	151
		Mean (std)	65.0 (43.69)	70.6 (40.88)
		Median	100.0	100.0
		Q1, Q3	0, 100.0	33.0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	149	145
		Mean (std)	60.8 (46.15)	65.8 (43.27)
		Median	100.0	100.0
		Q1, Q3	0, 100.0	33.0, 100.0
		Min, Max	-100, 100	-84, 100
Week 25	Actual	n	140	134
		Mean (std)	46.3 (46.22)	45.5 (47.65)
		Median	33.0	16.5
		Q1, Q3	0, 100.0	0, 100.0
		Min, Max	0, 100	0, 100
	Change from BL	n	137	129
		Mean (std)	41.3 (47.39)	42.9 (47.59)
		Median	33.0	0
		Q1, Q3	0, 100.0	0, 100.0
		Min, Max	-67, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	130
		Mean (std)	23.4 (38.86)	27.4 (43.24)
		Median	0	0
		Q1, Q3	0, 33.0	0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	126	126
		Mean (std)	19.2 (41.69)	24.1 (41.68)
		Median	0	0
		Q1, Q3	0, 33.0	0, 67.0
		Min, Max	-100, 100	-33, 100
Week 37	Actual	n	114	107
		Mean (std)	14.6 (32.00)	16.2 (34.70)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	111	104
		Mean (std)	10.2 (36.74)	14.1 (33.42)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	106	106
		Mean (std)	16.7 (34.51)	12.1 (27.45)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	104	103
		Mean (std)	12.2 (39.95)	9.5 (28.52)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-67, 100
Week 49	Actual	n	93	83
		Mean (std)	11.1 (29.21)	7.6 (25.14)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	91	81
		Mean (std)	7.0 (34.21)	5.8 (26.75)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	91	83
		Mean (std)	11.4 (29.08)	10.8 (27.58)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	89	81
		Mean (std)	7.9 (30.97)	8.2 (30.49)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 100	-67, 100
Week 61	Actual	n	81	66
		Mean (std)	12.3 (29.54)	11.6 (28.37)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	79	64
		Mean (std)	6.8 (35.10)	9.4 (28.79)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	8.5 (23.32)	10.0 (26.43)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	80	71
		Mean (std)	3.4 (27.84)	5.6 (30.83)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-100, 100
Week 73	Actual	n	76	62
		Mean (std)	14.0 (31.40)	8.6 (23.34)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	74	61
		Mean (std)	8.1 (35.64)	6.6 (24.95)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	65	57
		Mean (std)	11.3 (24.50)	10.5 (23.69)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	63	55
		Mean (std)	6.4 (27.29)	8.5 (25.00)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 100	-33, 100
Week 85	Actual	n	70	58
		Mean (std)	14.3 (28.13)	9.7 (21.57)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	68	58
		Mean (std)	8.4 (34.69)	5.7 (22.58)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	56	48
		Mean (std)	5.9 (15.69)	6.2 (16.35)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	54	48
		Mean (std)	1.9 (19.80)	4.2 (17.67)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-33, 67
Week 97	Actual	n	65	53
		Mean (std)	12.5 (24.61)	9.4 (22.97)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	63	52
		Mean (std)	7.7 (29.49)	5.8 (24.44)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-33, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	11.5 (23.27)	7.5 (20.13)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	54	42
		Mean (std)	4.9 (31.23)	4.7 (20.17)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-33, 100
Week 109	Actual	n	52	51
		Mean (std)	8.9 (22.95)	10.4 (20.55)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	51	51
		Mean (std)	4.6 (26.61)	7.2 (19.21)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	14.4 (30.75)	14.7 (31.11)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	49	41
		Mean (std)	7.5 (39.20)	9.7 (31.84)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-67, 100
Week 121	Actual	n	50	50
		Mean (std)	7.3 (15.41)	11.3 (22.94)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	49	50
		Mean (std)	2.7 (16.36)	9.3 (24.30)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	41
		Mean (std)	12.6 (25.90)	12.2 (26.62)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	44	41
		Mean (std)	5.3 (34.37)	7.3 (28.41)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-67, 100
Week 133	Actual	n	48	43
		Mean (std)	14.5 (26.54)	14.7 (27.52)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	46	42
		Mean (std)	8.0 (26.43)	10.3 (31.64)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	-33, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	8.6 (16.30)	6.9 (16.58)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 67
	Change from BL	n	45	36
		Mean (std)	1.5 (24.48)	4.2 (19.99)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 67	-33, 67
Week 145	Actual	n	38	31
		Mean (std)	19.3 (31.62)	9.6 (21.35)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	37	30
		Mean (std)	13.5 (32.80)	6.6 (23.71)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-33, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	25
		Mean (std)	15.7 (26.97)	9.3 (18.01)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	35	25
		Mean (std)	5.7 (36.51)	5.3 (18.34)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-100, 100	-33, 34
Week 157	Actual	n	26	20
		Mean (std)	16.6 (28.62)	3.3 (10.16)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 33
	Change from BL	n	26	19
		Mean (std)	10.2 (33.57)	1.7 (13.35)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-33, 100	-33, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	17
		Mean (std)	18.9 (19.84)	3.9 (10.96)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 67	0, 33
	Change from BL	n	21	17
		Mean (std)	14.2 (22.43)	1.9 (14.15)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-33, 67	-33, 33
Week 169	Actual	n	17	11
		Mean (std)	13.6 (26.45)	15.1 (22.91)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 67
	Change from BL	n	17	10
		Mean (std)	5.8 (39.42)	10.0 (27.40)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-100, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	19.3 (29.96)	6.0 (13.35)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 33
	Change from BL	n	12	11
		Mean (std)	16.6 (30.10)	3.0 (17.80)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	-33, 33
Week 181	Actual	n	9	8
		Mean (std)	14.8 (24.24)	0 (0)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 67	0, 0
	Change from BL	n	9	7
		Mean (std)	3.7 (45.48)	-4.7 (12.47)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-100, 67	-33, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	19.8 (18.07)	0 (0)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 33	0, 0
	Change from BL	n	5	2
		Mean (std)	19.8 (18.07)	0 (0)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 33	0, 0
Week 193	Actual	n	1	0
		Mean (std)	0	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	0	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	12.7 (29.74)	12.5 (28.57)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	180	172
		Mean (std)	8.0 (33.31)	8.3 (29.54)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-100, 100	-100, 100
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	97.3 (12.00)	95.9 (14.02)
		Median	100.0	100.0
		Q1, Q3	100.0, 100.0	100.0, 100.0
		Min, Max	0, 100	33, 100
	Change from BL	n	180	172
		Mean (std)	92.6 (19.11)	92.1 (19.94)
		Median	100.0	100.0
		Q1, Q3	100.0, 100.0	100.0, 100.0
		Min, Max	0, 100	0, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	186	174
		Mean (std)	7.3 (17.97)	6.7 (18.23)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
Week 4	Actual	n	179	176
		Mean (std)	25.3 (28.53)	20.1 (26.39)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	177	170
		Mean (std)	19.1 (27.75)	13.8 (23.88)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-34, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	167
		Mean (std)	30.5 (32.09)	25.3 (30.00)
		Median	33.0	33.0
		Q1, Q3	0, 41.5	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	169	161
		Mean (std)	25.1 (32.58)	19.6 (30.80)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-34, 100	-67, 100
Week 10	Actual	n	167	158
		Mean (std)	30.7 (33.16)	25.2 (29.27)
		Median	33.0	33.0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	164	152
		Mean (std)	24.3 (33.87)	21.2 (28.33)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-34, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	160	150
		Mean (std)	32.8 (34.64)	27.5 (31.82)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	157	144
		Mean (std)	26.0 (35.60)	22.4 (30.75)
		Median	33.0	0
		Q1, Q3	0, 34.0	0, 33.0
		Min, Max	-34, 100	-33, 100
Week 16	Actual	n	155	152
		Mean (std)	33.8 (34.59)	28.9 (30.18)
		Median	33.0	33.0
		Q1, Q3	0, 67.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	152	146
		Mean (std)	26.4 (35.47)	23.2 (29.91)
		Median	33.0	33.0
		Q1, Q3	0, 50.5	0, 33.0
		Min, Max	-67, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	30.5 (32.27)	19.4 (26.12)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	153	146
		Mean (std)	23.3 (34.44)	14.8 (26.66)
		Median	33.0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	-67, 100	-50, 100
Week 25	Actual	n	140	134
		Mean (std)	19.6 (28.52)	11.6 (21.71)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	138	129
		Mean (std)	13.4 (29.17)	7.0 (21.46)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-67, 100	-33, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	133
		Mean (std)	13.6 (24.93)	12.7 (23.44)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	127	129
		Mean (std)	6.8 (26.04)	7.7 (23.30)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-33, 100
Week 37	Actual	n	115	108
		Mean (std)	12.1 (24.27)	7.8 (16.73)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	113	105
		Mean (std)	6.2 (26.10)	3.9 (18.62)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	107	107
		Mean (std)	12.1 (26.06)	9.3 (20.86)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	106	104
		Mean (std)	4.7 (25.36)	4.8 (21.43)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 100	-33, 100
Week 49	Actual	n	94	83
		Mean (std)	11.9 (24.52)	8.8 (18.02)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	92	81
		Mean (std)	6.0 (27.10)	4.9 (19.75)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	92	83
		Mean (std)	10.4 (20.87)	12.4 (24.80)
		Median	0	0
		Q1, Q3	0, 16.5	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	90	81
		Mean (std)	3.3 (22.84)	8.2 (26.61)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-67, 100
Week 61	Actual	n	81	66
		Mean (std)	11.9 (23.75)	8.1 (19.48)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	79	64
		Mean (std)	4.2 (27.36)	3.2 (20.33)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	82	73
		Mean (std)	10.1 (19.37)	11.8 (25.06)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	80	71
		Mean (std)	4.2 (21.40)	6.1 (22.70)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-33, 100
Week 73	Actual	n	76	62
		Mean (std)	10.5 (21.87)	12.9 (24.44)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	74	61
		Mean (std)	5.4 (25.22)	7.1 (22.83)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	66	58
		Mean (std)	8.5 (18.71)	10.9 (24.50)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	64	56
		Mean (std)	1.6 (20.78)	5.4 (25.20)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 67	-33, 100
Week 85	Actual	n	70	58
		Mean (std)	11.4 (23.95)	12.0 (23.11)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	68	58
		Mean (std)	4.4 (23.61)	8.0 (20.99)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	56	48
		Mean (std)	14.2 (25.30)	6.9 (15.24)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	54	48
		Mean (std)	6.2 (25.91)	3.4 (20.83)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	-34, 67	-67, 67
Week 97	Actual	n	65	53
		Mean (std)	12.0 (26.57)	6.2 (14.63)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	63	52
		Mean (std)	5.5 (28.81)	1.9 (19.09)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	16.3 (26.35)	7.5 (20.13)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	54	42
		Mean (std)	7.4 (30.09)	2.4 (21.34)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 100	-67, 67
Week 109	Actual	n	52	51
		Mean (std)	12.1 (26.40)	7.1 (15.29)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	51	51
		Mean (std)	6.5 (29.79)	2.6 (20.83)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 100	-67, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	13.1 (28.36)	7.0 (17.14)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	49	41
		Mean (std)	4.1 (25.11)	1.6 (21.04)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 100	-67, 67
Week 121	Actual	n	50	50
		Mean (std)	8.6 (16.14)	11.3 (21.90)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 67	0, 100
	Change from BL	n	49	50
		Mean (std)	2.7 (18.89)	5.3 (23.63)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 34	-34, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	41
		Mean (std)	9.6 (18.25)	8.1 (19.33)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	44	41
		Mean (std)	-0.8 (24.35)	3.2 (24.43)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-67, 100
Week 133	Actual	n	48	43
		Mean (std)	15.9 (30.74)	13.9 (27.45)
		Median	0	0
		Q1, Q3	0, 33.0	0, 33.0
		Min, Max	0, 100	0, 100
	Change from BL	n	46	42
		Mean (std)	9.4 (31.13)	9.5 (25.82)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 100	-33, 67

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	10.8 (26.31)	10.2 (23.67)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 100	0, 100
	Change from BL	n	45	36
		Mean (std)	1.5 (28.32)	5.6 (25.85)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 100	-67, 100
Week 145	Actual	n	38	31
		Mean (std)	13.1 (23.92)	5.3 (12.34)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 33
	Change from BL	n	37	30
		Mean (std)	5.4 (27.70)	0 (19.50)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 100	-67, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	25
		Mean (std)	15.7 (29.28)	4.0 (10.94)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 33
	Change from BL	n	35	25
		Mean (std)	4.8 (26.99)	-1.4 (17.92)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-34, 100	-67, 33
Week 157	Actual	n	26	20
		Mean (std)	6.3 (13.26)	1.7 (7.38)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 33	0, 33
	Change from BL	n	26	19
		Mean (std)	1.3 (19.76)	0 (11.00)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 33	-33, 33

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	20	17
		Mean (std)	15.0 (27.51)	3.9 (16.25)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 100	0, 67
	Change from BL	n	20	17
		Mean (std)	10.0 (30.72)	2.0 (8.25)
		Median	0	0
		Q1, Q3	0, 16.5	0, 0
		Min, Max	-33, 100	0, 34
Week 169	Actual	n	17	11
		Mean (std)	5.8 (12.97)	21.2 (40.19)
		Median	0	0
		Q1, Q3	0, 0	0, 33.0
		Min, Max	0, 33	0, 100
	Change from BL	n	17	10
		Mean (std)	-2.0 (24.83)	16.7 (36.06)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 33	0, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	2.8 (9.53)	0 (0)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 33	0, 0
	Change from BL	n	12	11
		Mean (std)	0 (14.07)	0 (0)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-33, 33	0, 0
Week 181	Actual	n	9	8
		Mean (std)	40.8 (43.45)	4.1 (11.67)
		Median	33.0	0
		Q1, Q3	0, 67.0	0, 0
		Min, Max	0, 100	0, 33
	Change from BL	n	9	7
		Mean (std)	22.3 (55.33)	-4.7 (12.47)
		Median	0	0
		Q1, Q3	-33.0, 67.0	0, 0
		Min, Max	-34, 100	-33, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	13.2 (18.07)	0 (0)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 33	0, 0
	Change from BL	n	5	2
		Mean (std)	13.2 (18.07)	0 (0)
		Median	0	0
		Q1, Q3	0, 33.0	0, 0
		Min, Max	0, 33	0, 0
Week 193	Actual	n	1	0
		Mean (std)	0	
		Median	0	
		Q1, Q3	0, 0	
		Min, Max	0, 0	
	Change from BL	n	1	0
		Mean (std)	-33.0	
		Median	-33.0	
		Q1, Q3	-33.0, -33.0	
		Min, Max	-33, -33	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		33.0
		Median		33.0
		Q1, Q3		33.0, 33.0
		Min, Max		33, 33
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
Week 205	Actual	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0
	Change from BL	n	0	1
		Mean (std)		0
		Median		0
		Q1, Q3		0, 0
		Min, Max		0, 0

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
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Table 2.1702 Summary of Actual and Change from Baseline in EORTC-QLQ-EN24 Domain Score Over Time (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	4.7 (13.06)	4.7 (14.91)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	0, 67	0, 100
	Change from BL	n	181	172
		Mean (std)	-1.7 (18.28)	-1.5 (17.16)
		Median	0	0
		Q1, Q3	0, 0	0, 0
		Min, Max	-67, 67	-67, 67
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	56.1 (36.94)	46.9 (33.44)
		Median	67.0	33.0
		Q1, Q3	33.0, 100.0	33.0, 67.0
		Min, Max	0, 100	0, 100
	Change from BL	n	181	172
		Mean (std)	49.4 (38.33)	40.5 (33.42)
		Median	34.0	33.0
		Q1, Q3	33.0, 67.0	16.5, 67.0
		Min, Max	-34, 100	-67, 100

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_1702_en24_cfb.sas, Output: t_2_1702_en24_cfb.rtf, Generated on: 24JUL2024 14:18,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Baseline	Actual	n	185	176
		Mean (std)	75.8 (17.10)	76.1 (18.46)
		Median	80.0	80.0
		Q1, Q3	65.0, 90.0	70.0, 90.0
		Min, Max	25, 100	10, 100
Week 4	Actual	n	178	174
		Mean (std)	76.2 (16.53)	78.5 (16.41)
		Median	80.0	80.0
		Q1, Q3	70.0, 90.0	70.0, 90.0
		Min, Max	10, 100	30, 100
	Change from BL	n	175	171
		Mean (std)	-0.1 (13.37)	2.1 (15.07)
		Median	0	0
		Q1, Q3	-8.0, 5.0	-5.0, 10.0
		Min, Max	-40, 45	-30, 70

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,

Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 7	Actual	n	172	166
		Mean (std)	76.9 (16.57)	78.7 (15.12)
		Median	80.0	80.0
		Q1, Q3	70.0, 90.0	70.0, 90.0
		Min, Max	20, 100	25, 100
	Change from BL	n	168	163
		Mean (std)	0.7 (14.83)	2.4 (13.06)
		Median	0	0
		Q1, Q3	-6.5, 7.5	-5.0, 10.0
		Min, Max	-60, 50	-55, 50
Week 10	Actual	n	169	159
		Mean (std)	76.0 (17.86)	78.3 (15.84)
		Median	80.0	80.0
		Q1, Q3	65.0, 90.0	65.0, 90.0
		Min, Max	10, 100	40, 100
	Change from BL	n	165	155
		Mean (std)	-0.7 (16.03)	1.1 (13.12)
		Median	0	0
		Q1, Q3	-10.0, 8.0	-5.0, 9.0
		Min, Max	-70, 53	-35, 50

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 13	Actual	n	159	151
		Mean (std)	76.2 (16.91)	77.5 (17.92)
		Median	80.0	80.0
		Q1, Q3	65.0, 90.0	70.0, 90.0
		Min, Max	25, 100	0, 100
	Change from BL	n	155	148
		Mean (std)	0.4 (16.14)	0.4 (18.01)
		Median	0	0
		Q1, Q3	-10.0, 10.0	-8.8, 10.0
		Min, Max	-45, 50	-99, 90
Week 16	Actual	n	155	152
		Mean (std)	76.0 (18.77)	77.4 (17.68)
		Median	80.0	80.0
		Q1, Q3	65.0, 90.0	70.0, 90.0
		Min, Max	10, 100	10, 100
	Change from BL	n	151	148
		Mean (std)	0.1 (17.88)	0.5 (17.34)
		Median	0	0
		Q1, Q3	-10.0, 10.0	-9.5, 8.5
		Min, Max	-70, 55	-55, 55

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,

Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 19	Actual	n	156	152
		Mean (std)	74.3 (18.34)	78.8 (16.15)
		Median	75.0	80.0
		Q1, Q3	62.5, 90.0	70.0, 90.0
		Min, Max	20, 100	30, 100
	Change from BL	n	153	148
		Mean (std)	-2.4 (17.68)	1.8 (16.63)
		Median	0	0
		Q1, Q3	-10.0, 7.5	-5.0, 10.0
		Min, Max	-50, 40	-45, 70
Week 25	Actual	n	139	135
		Mean (std)	76.0 (18.64)	79.6 (18.43)
		Median	80.0	85.0
		Q1, Q3	65.0, 90.0	70.0, 95.0
		Min, Max	20, 100	0, 100
	Change from BL	n	136	131
		Mean (std)	1.1 (17.78)	2.6 (18.77)
		Median	0	5.0
		Q1, Q3	-10.0, 10.0	-5.0, 10.0
		Min, Max	-55, 50	-80, 70

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 31	Actual	n	129	132
		Mean (std)	78.1 (17.55)	81.4 (15.65)
		Median	80.0	85.0
		Q1, Q3	70.0, 93.0	75.0, 95.0
		Min, Max	20, 100	20, 100
	Change from BL	n	126	130
		Mean (std)	0.8 (18.16)	4.1 (16.00)
		Median	0	5.0
		Q1, Q3	-10.0, 10.0	-5.0, 10.0
		Min, Max	-68, 50	-60, 70
Week 37	Actual	n	116	108
		Mean (std)	81.1 (15.89)	80.4 (14.79)
		Median	85.0	85.0
		Q1, Q3	75.0, 95.0	70.0, 90.0
		Min, Max	30, 100	30, 100
	Change from BL	n	114	106
		Mean (std)	3.4 (18.06)	2.5 (18.10)
		Median	0	5.0
		Q1, Q3	-8.0, 15.0	-8.0, 10.0
		Min, Max	-50, 55	-55, 60

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 43	Actual	n	107	107
		Mean (std)	80.9 (15.44)	82.0 (13.74)
		Median	85.0	85.0
		Q1, Q3	75.0, 95.0	75.0, 90.0
		Min, Max	30, 100	30, 100
	Change from BL	n	106	105
		Mean (std)	2.1 (16.91)	3.4 (16.63)
		Median	0	1.0
		Q1, Q3	-10.0, 10.0	-2.0, 10.0
		Min, Max	-40, 50	-69, 60
Week 49	Actual	n	93	82
		Mean (std)	79.4 (17.76)	81.8 (15.67)
		Median	80.0	85.0
		Q1, Q3	70.0, 95.0	75.0, 90.0
		Min, Max	25, 100	20, 100
	Change from BL	n	90	82
		Mean (std)	1.2 (17.67)	4.2 (18.97)
		Median	0	0.5
		Q1, Q3	-5.0, 10.0	-2.0, 10.0
		Min, Max	-40, 50	-70, 70

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 55	Actual	n	93	84
		Mean (std)	79.7 (17.87)	78.6 (15.86)
		Median	85.0	80.0
		Q1, Q3	70.0, 95.0	70.0, 90.0
		Min, Max	25, 100	25, 100
	Change from BL	n	91	82
		Mean (std)	1.4 (18.87)	0.9 (19.62)
		Median	0	0
		Q1, Q3	-5.0, 10.0	-5.0, 10.0
		Min, Max	-70, 50	-70, 50
Week 61	Actual	n	80	66
		Mean (std)	80.6 (16.43)	81.9 (15.80)
		Median	80.0	85.0
		Q1, Q3	70.0, 95.0	75.0, 90.0
		Min, Max	35, 100	2, 100
	Change from BL	n	77	66
		Mean (std)	2.2 (18.03)	4.7 (21.00)
		Median	0	0
		Q1, Q3	-5.0, 10.0	-5.0, 10.0
		Min, Max	-50, 50	-97, 70

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 67	Actual	n	83	73
		Mean (std)	81.1 (17.48)	83.0 (12.16)
		Median	85.0	85.0
		Q1, Q3	70.0, 95.0	78.0, 90.0
		Min, Max	25, 100	50, 100
	Change from BL	n	81	72
		Mean (std)	3.2 (18.51)	3.4 (15.51)
		Median	0	0
		Q1, Q3	-5.0, 15.0	-5.0, 10.0
		Min, Max	-50, 50	-30, 50
Week 73	Actual	n	76	62
		Mean (std)	80.7 (15.02)	79.8 (17.91)
		Median	84.0	85.0
		Q1, Q3	73.5, 94.5	70.0, 95.0
		Min, Max	40, 100	8, 100
	Change from BL	n	74	62
		Mean (std)	1.4 (17.98)	2.6 (17.88)
		Median	0	0
		Q1, Q3	-10.0, 10.0	-5.0, 10.0
		Min, Max	-50, 50	-55, 60

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,

Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 79	Actual	n	67	58
		Mean (std)	81.1 (16.95)	81.4 (16.85)
		Median	85.0	85.0
		Q1, Q3	75.0, 95.0	75.0, 95.0
		Min, Max	25, 100	20, 100
	Change from BL	n	64	57
		Mean (std)	1.3 (17.62)	3.1 (17.33)
		Median	0	5.0
		Q1, Q3	-10.0, 10.0	-5.0, 10.0
		Min, Max	-40, 55	-50, 65
Week 85	Actual	n	70	58
		Mean (std)	79.2 (15.92)	80.3 (16.91)
		Median	80.0	85.0
		Q1, Q3	72.0, 90.0	75.0, 92.0
		Min, Max	35, 100	35, 100
	Change from BL	n	67	58
		Mean (std)	1.4 (16.14)	3.9 (18.42)
		Median	0	5.0
		Q1, Q3	-5.0, 15.0	-5.0, 10.0
		Min, Max	-50, 40	-45, 65

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 91	Actual	n	56	50
		Mean (std)	80.3 (18.35)	83.5 (12.96)
		Median	85.0	85.0
		Q1, Q3	75.0, 95.0	75.0, 95.0
		Min, Max	10, 100	50, 100
	Change from BL	n	54	49
		Mean (std)	1.4 (21.43)	5.6 (19.91)
		Median	0	0
		Q1, Q3	-5.0, 15.0	-5.0, 10.0
		Min, Max	-70, 50	-20, 75
Week 97	Actual	n	65	52
		Mean (std)	79.8 (16.09)	79.6 (15.72)
		Median	85.0	80.5
		Q1, Q3	70.0, 90.0	75.0, 90.0
		Min, Max	40, 100	20, 100
	Change from BL	n	63	52
		Mean (std)	1.5 (17.98)	4.7 (21.17)
		Median	0	0
		Q1, Q3	-5.0, 15.0	-5.0, 15.0
		Min, Max	-58, 50	-60, 75

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 103	Actual	n	55	44
		Mean (std)	79.6 (17.38)	84.2 (12.48)
		Median	85.0	85.5
		Q1, Q3	70.0, 95.0	75.0, 95.0
		Min, Max	30, 100	50, 100
	Change from BL	n	53	43
		Mean (std)	3.9 (17.07)	7.2 (19.86)
		Median	0	5.0
		Q1, Q3	-5.0, 15.0	-5.0, 10.0
		Min, Max	-30, 50	-25, 75
Week 109	Actual	n	52	51
		Mean (std)	81.5 (16.00)	84.5 (11.03)
		Median	85.0	85.0
		Q1, Q3	75.0, 95.0	76.0, 95.0
		Min, Max	30, 100	60, 100
	Change from BL	n	51	51
		Mean (std)	3.6 (19.65)	7.2 (18.39)
		Median	0	5.0
		Q1, Q3	-5.0, 15.0	-5.0, 15.0
		Min, Max	-70, 50	-20, 75

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 115	Actual	n	51	43
		Mean (std)	81.3 (17.62)	80.1 (18.22)
		Median	85.0	83.0
		Q1, Q3	75.0, 95.0	70.0, 95.0
		Min, Max	30, 100	20, 100
	Change from BL	n	48	42
		Mean (std)	4.0 (16.14)	4.6 (19.74)
		Median	0	2.5
		Q1, Q3	-5.0, 11.0	-5.0, 10.0
		Min, Max	-30, 50	-30, 65
Week 121	Actual	n	51	50
		Mean (std)	83.1 (15.01)	81.4 (14.84)
		Median	85.0	83.5
		Q1, Q3	75.0, 95.0	75.0, 93.0
		Min, Max	40, 100	30, 100
	Change from BL	n	50	50
		Mean (std)	3.9 (15.48)	2.3 (17.19)
		Median	0	0
		Q1, Q3	-5.0, 10.0	-10.0, 10.0
		Min, Max	-25, 45	-40, 50

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 127	Actual	n	45	43
		Mean (std)	81.2 (17.23)	81.3 (15.50)
		Median	85.0	85.0
		Q1, Q3	70.0, 95.0	70.0, 95.0
		Min, Max	40, 100	43, 100
	Change from BL	n	44	43
		Mean (std)	3.7 (17.88)	7.5 (17.32)
		Median	0	5.0
		Q1, Q3	-5.0, 15.0	-5.0, 15.0
		Min, Max	-30, 50	-25, 50
Week 133	Actual	n	47	43
		Mean (std)	84.2 (14.21)	82.8 (13.05)
		Median	90.0	85.0
		Q1, Q3	75.0, 95.0	75.0, 95.0
		Min, Max	45, 100	40, 100
	Change from BL	n	45	43
		Mean (std)	6.6 (17.55)	4.4 (17.35)
		Median	5.0	0
		Q1, Q3	-1.0, 15.0	-10.0, 10.0
		Min, Max	-50, 50	-30, 47

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 139	Actual	n	46	36
		Mean (std)	80.4 (17.21)	81.4 (13.43)
		Median	83.5	81.5
		Q1, Q3	70.0, 95.0	70.0, 95.0
		Min, Max	25, 100	55, 100
	Change from BL	n	44	36
		Mean (std)	2.3 (19.42)	6.8 (20.82)
		Median	0	3.0
		Q1, Q3	-10.0, 12.5	-5.0, 16.0
		Min, Max	-51, 50	-25, 60
Week 145	Actual	n	38	31
		Mean (std)	84.8 (13.66)	87.7 (10.01)
		Median	87.0	90.0
		Q1, Q3	80.0, 95.0	80.0, 95.0
		Min, Max	35, 99	60, 100
	Change from BL	n	37	31
		Mean (std)	4.6 (16.31)	7.5 (21.03)
		Median	5.0	5.0
		Q1, Q3	-5.0, 15.0	-5.0, 10.0
		Min, Max	-25, 45	-20, 80

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 151	Actual	n	36	24
		Mean (std)	79.1 (18.44)	84.5 (13.88)
		Median	80.0	87.5
		Q1, Q3	70.0, 95.0	75.0, 95.5
		Min, Max	35, 100	50, 100
	Change from BL	n	34	24
		Mean (std)	1.7 (19.52)	8.0 (25.20)
		Median	0	4.5
		Q1, Q3	-5.0, 10.0	-5.0, 10.0
		Min, Max	-58, 50	-40, 75
Week 157	Actual	n	26	21
		Mean (std)	82.7 (19.15)	82.1 (15.62)
		Median	92.5	90.0
		Q1, Q3	75.0, 95.0	70.0, 91.0
		Min, Max	35, 100	45, 100
	Change from BL	n	26	21
		Mean (std)	1.2 (16.14)	6.6 (16.89)
		Median	0	5.0
		Q1, Q3	-5.0, 5.0	-5.0, 10.0
		Min, Max	-30, 50	-10, 48

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 163	Actual	n	21	18
		Mean (std)	78.2 (19.88)	83.3 (13.66)
		Median	85.0	85.0
		Q1, Q3	70.0, 95.0	80.0, 95.0
		Min, Max	30, 98	50, 100
	Change from BL	n	21	18
		Mean (std)	1.0 (16.90)	6.6 (21.37)
		Median	0	0
		Q1, Q3	-8.0, 5.0	0, 10.0
		Min, Max	-25, 45	-30, 57
Week 169	Actual	n	17	10
		Mean (std)	85.2 (15.24)	86.9 (13.52)
		Median	90.0	92.0
		Q1, Q3	80.0, 95.0	85.0, 95.0
		Min, Max	40, 100	60, 100
	Change from BL	n	17	10
		Mean (std)	5.2 (20.40)	6.0 (10.18)
		Median	4.0	5.0
		Q1, Q3	-5.0, 15.0	1.0, 10.0
		Min, Max	-35, 50	-10, 30

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.

Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,

Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 175	Actual	n	12	11
		Mean (std)	76.5 (17.26)	83.9 (11.96)
		Median	80.0	90.0
		Q1, Q3	62.5, 92.5	75.0, 95.0
		Min, Max	50, 98	60, 98
	Change from BL	n	12	11
		Mean (std)	-4.2 (17.11)	3.0 (12.00)
		Median	-5.0	0
		Q1, Q3	-15.0, 5.0	-10.0, 8.0
		Min, Max	-30, 30	-10, 30
Week 181	Actual	n	9	8
		Mean (std)	75.0 (15.61)	86.3 (14.54)
		Median	80.0	95.0
		Q1, Q3	60.0, 80.0	75.0, 95.5
		Min, Max	50, 95	60, 99
	Change from BL	n	9	8
		Mean (std)	-3.9 (26.55)	6.4 (12.92)
		Median	-10.0	5.0
		Q1, Q3	-15.0, 15.0	0.5, 7.5
		Min, Max	-50, 40	-10, 35

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 187	Actual	n	5	2
		Mean (std)	66.0 (24.85)	87.5 (10.61)
		Median	70.0	87.5
		Q1, Q3	55.0, 80.0	80.0, 95.0
		Min, Max	30, 95	80, 95
	Change from BL	n	5	2
		Mean (std)	-6.0 (29.03)	-2.5 (10.61)
		Median	-20.0	-2.5
		Q1, Q3	-25.0, 5.0	-10.0, 5.0
		Min, Max	-30, 40	-10, 5
Week 193	Actual	n	1	0
		Mean (std)	95.0 (-)	
		Median	95.0	
		Q1, Q3	95.0, 95.0	
		Min, Max	95, 95	
	Change from BL	n	1	0
		Mean (std)	15.0 (-)	
		Median	15.0	
		Q1, Q3	15.0, 15.0	
		Min, Max	15, 15	

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Week 199	Actual	n	0	1
		Mean (std)		95.0 (-)
		Median		95.0
		Q1, Q3		95.0, 95.0
		Min, Max		95, 95
	Change from BL	n	0	1
		Mean (std)		20.0 (-)
		Median		20.0
		Q1, Q3		20.0, 20.0
		Min, Max		20, 20
Week 205	Actual	n	0	1
		Mean (std)		100.0 (-)
		Median		100.0
		Q1, Q3		100.0, 100.0
		Min, Max		100, 100
	Change from BL	n	0	1
		Mean (std)		10.0 (-)
		Median		10.0
		Q1, Q3		10.0, 10.0
		Min, Max		10, 10

n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

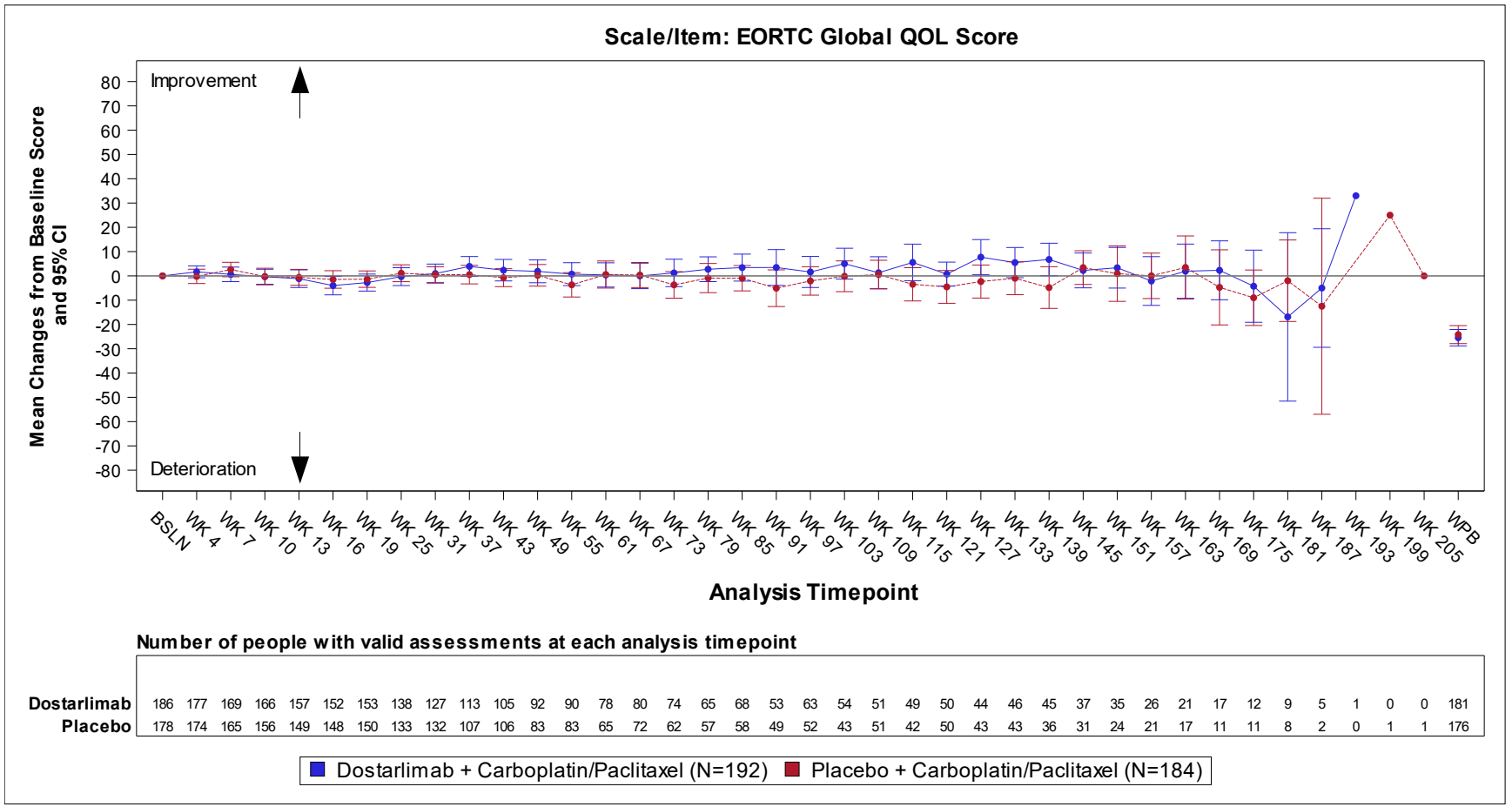
Table 2.2402 Summary of Actual and Change from Baseline in EQ-5D-5L Visual Analogue Scores Over Time (ITT Analysis Set): MMRp/MSS Subjects

MMR/MSI status: MMRp/MSS

Analysis Timepoint	Actual/ Change	Statistic	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Post-Baseline Minimum	Actual	n	184	178
		Mean (std)	57.9 (20.48)	59.8 (21.45)
		Median	60.0	60.0
		Q1, Q3	45.0, 75.0	49.0, 75.0
		Min, Max	10, 100	0, 100
	Change from BL	n	180	174
		Mean (std)	-18.1 (20.15)	-16.1 (20.86)
		Median	-15.0	-15.0
		Q1, Q3	-30.0, -5.0	-30.0, 0
		Min, Max	-70, 45	-99, 55
Post-Baseline Maximum	Actual	n	184	178
		Mean (std)	86.5 (12.32)	88.1 (11.62)
		Median	90.0	90.0
		Q1, Q3	80.0, 95.0	80.0, 98.0
		Min, Max	50, 100	50, 100
	Change from BL	n	180	174
		Mean (std)	10.5 (14.97)	12.0 (15.71)
		Median	10.0	10.0
		Q1, Q3	0, 19.5	0, 18.0
		Min, Max	-30, 55	-15, 90

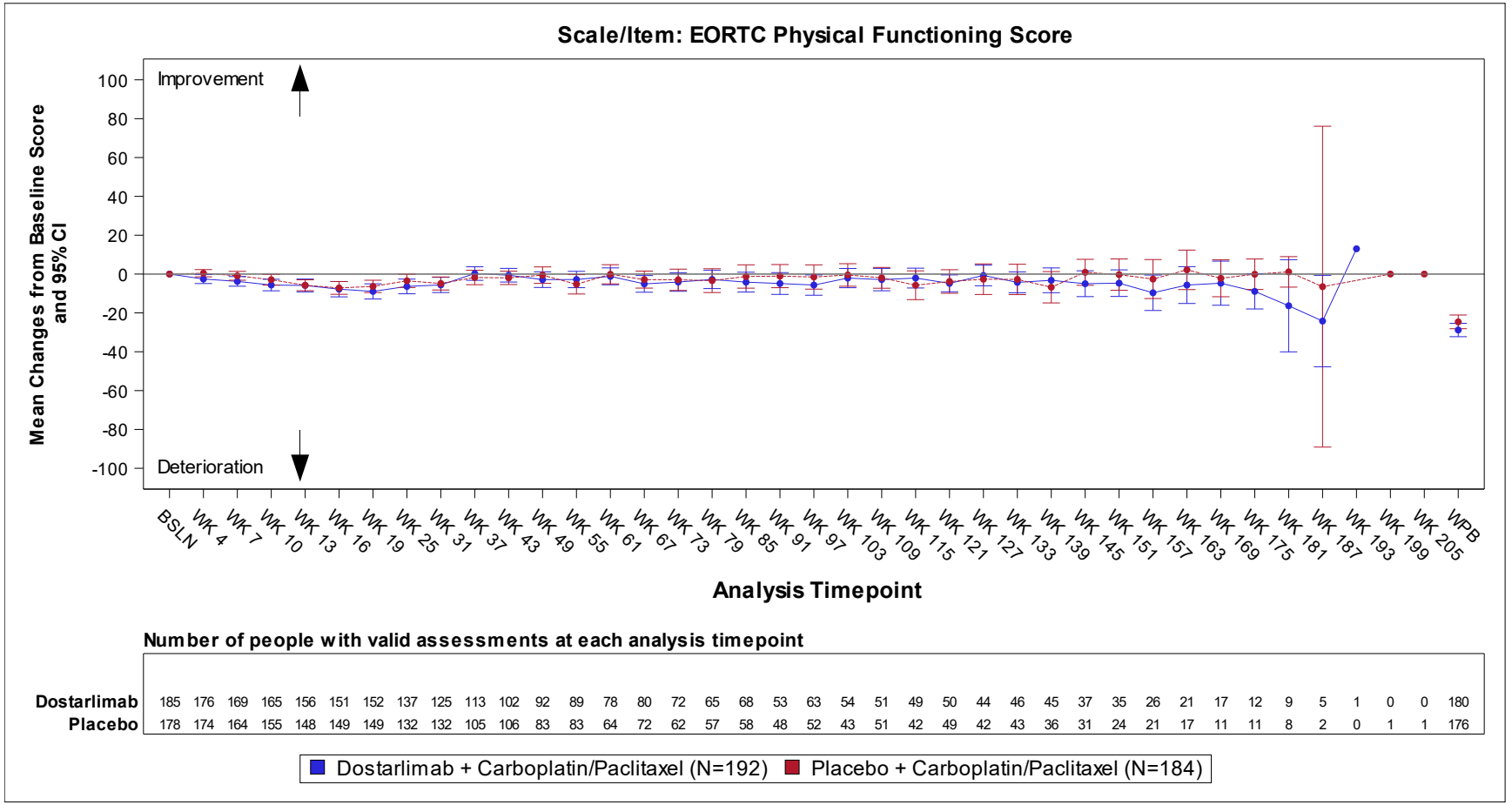
n for “Actual” is number of subjects with non-missing values at the analysis timepoint. n for “Change from BL” is number of subjects with non-missing values at both baseline and the analysis timepoint.
Program: t_2_2402_eq5d5l_cfb.sas, Output: t_2_2402_eq5d5l_cfb.rtf, Generated on: 31JUL2024 15:53,
Data Cutoff Date: 22SEP2023

Figure 2.0902 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-C30 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_0902_q30_cfb.sas, Output: f_2_0902_q30_cfb.rtf, Generated on: 02AUG2024 07:27,
Data Cutoff Date: 22SEP2023

Figure 2.0902 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-C30 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_0902_q30_cfb.sas, Output: f_2_0902_q30_cfb.rtf, Generated on: 02AUG2024 07:27,
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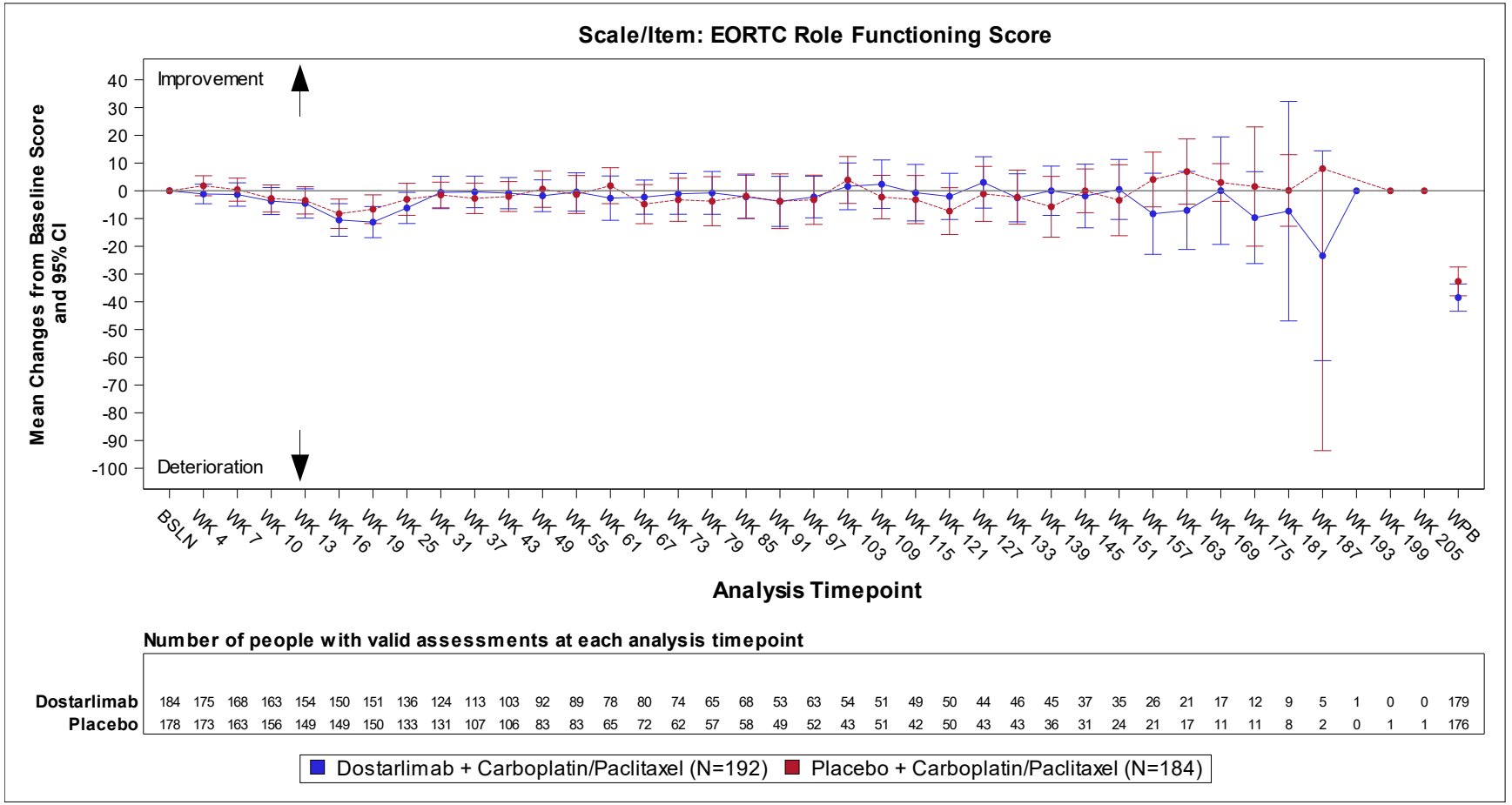

BSLN=Baseline WPB=Worst Post-Baseline
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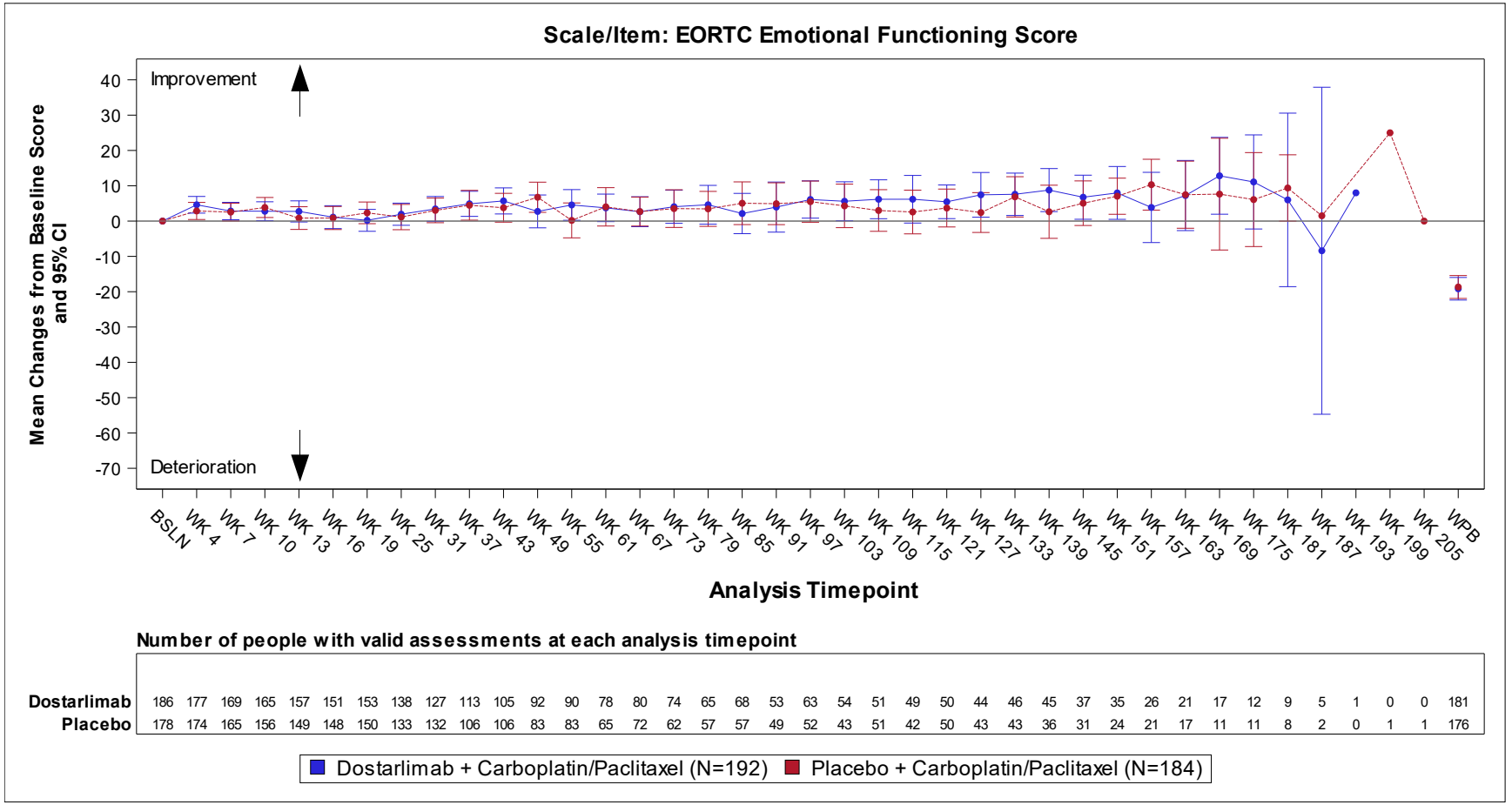

BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
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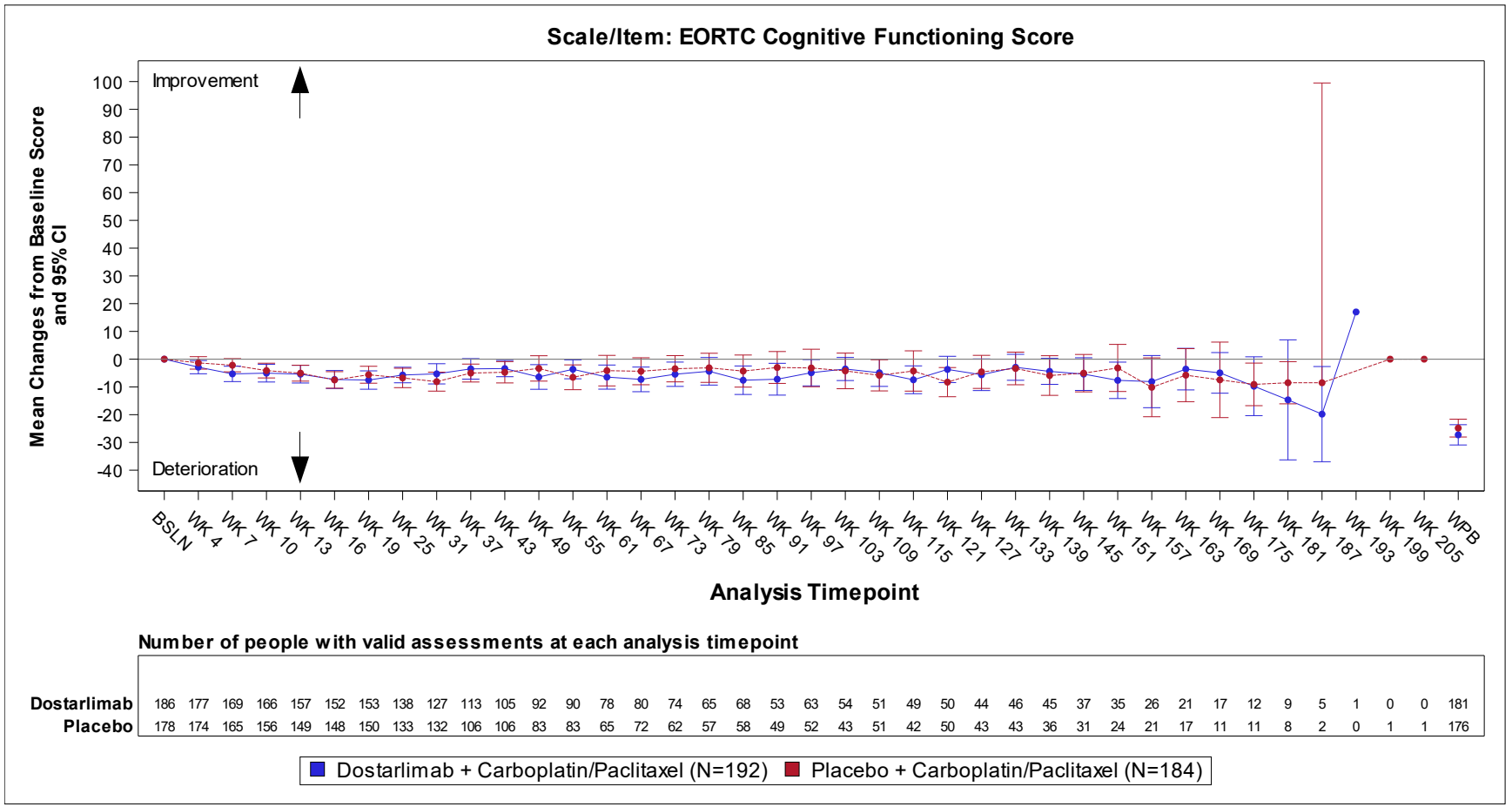

BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_0902_q30_cfb.sas, Output: f_2_0902_q30_cfb.rtf, Generated on: 02AUG2024 07:27,
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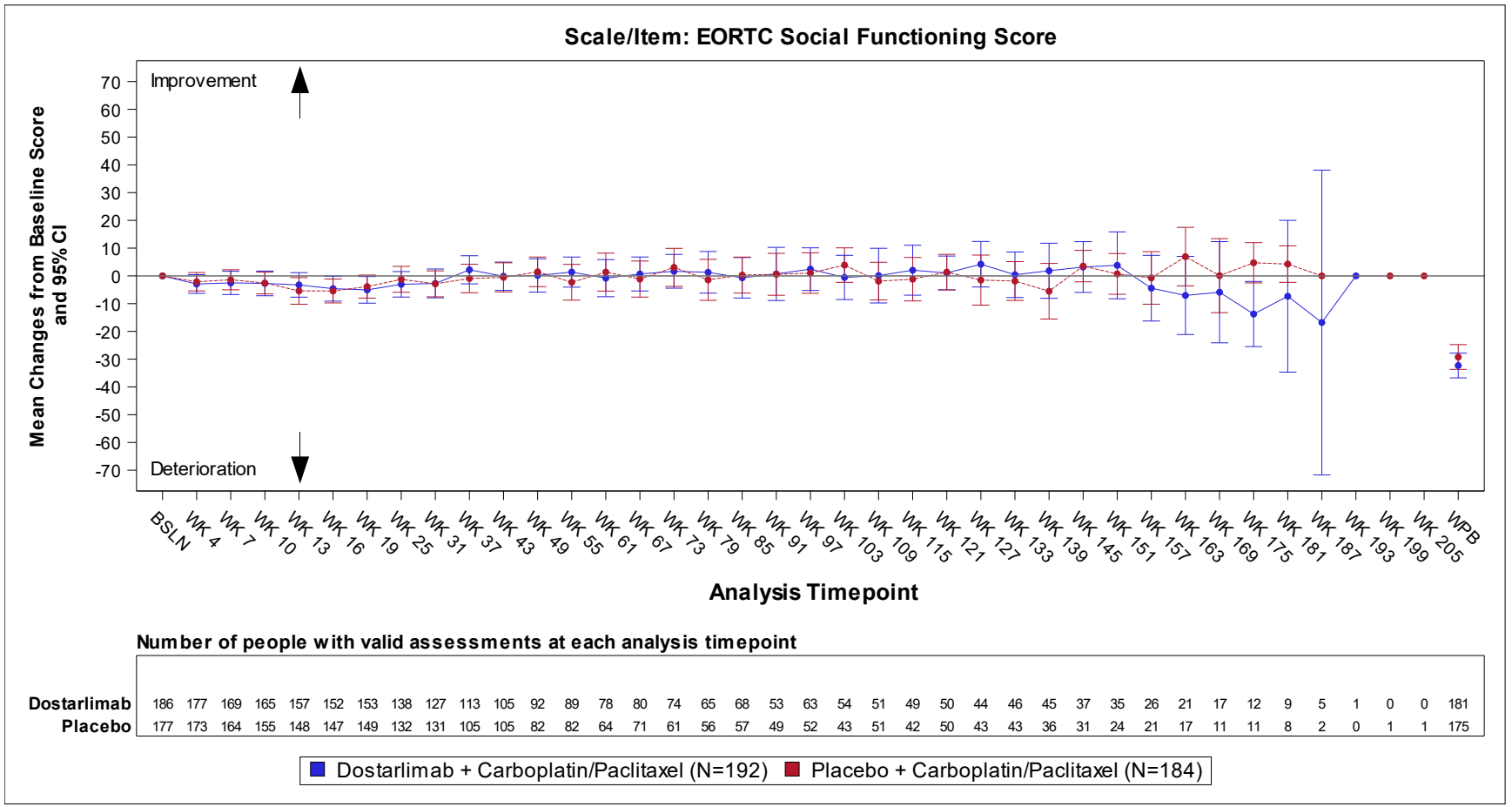

BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_0902_q30_cfb.sas, Output: f_2_0902_q30_cfb.rtf, Generated on: 02AUG2024 07:27,
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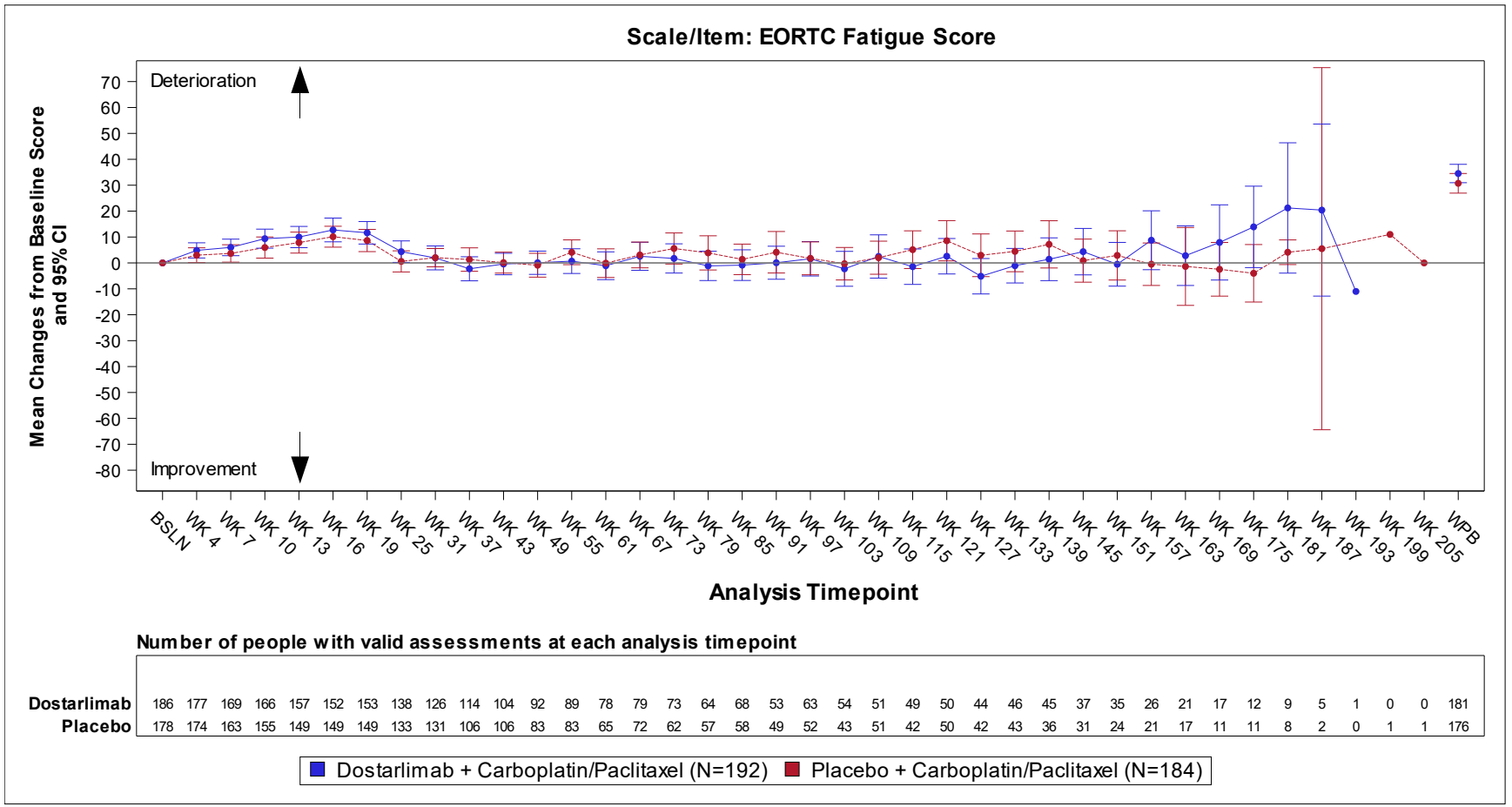
Figure 2.0902 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-C30 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
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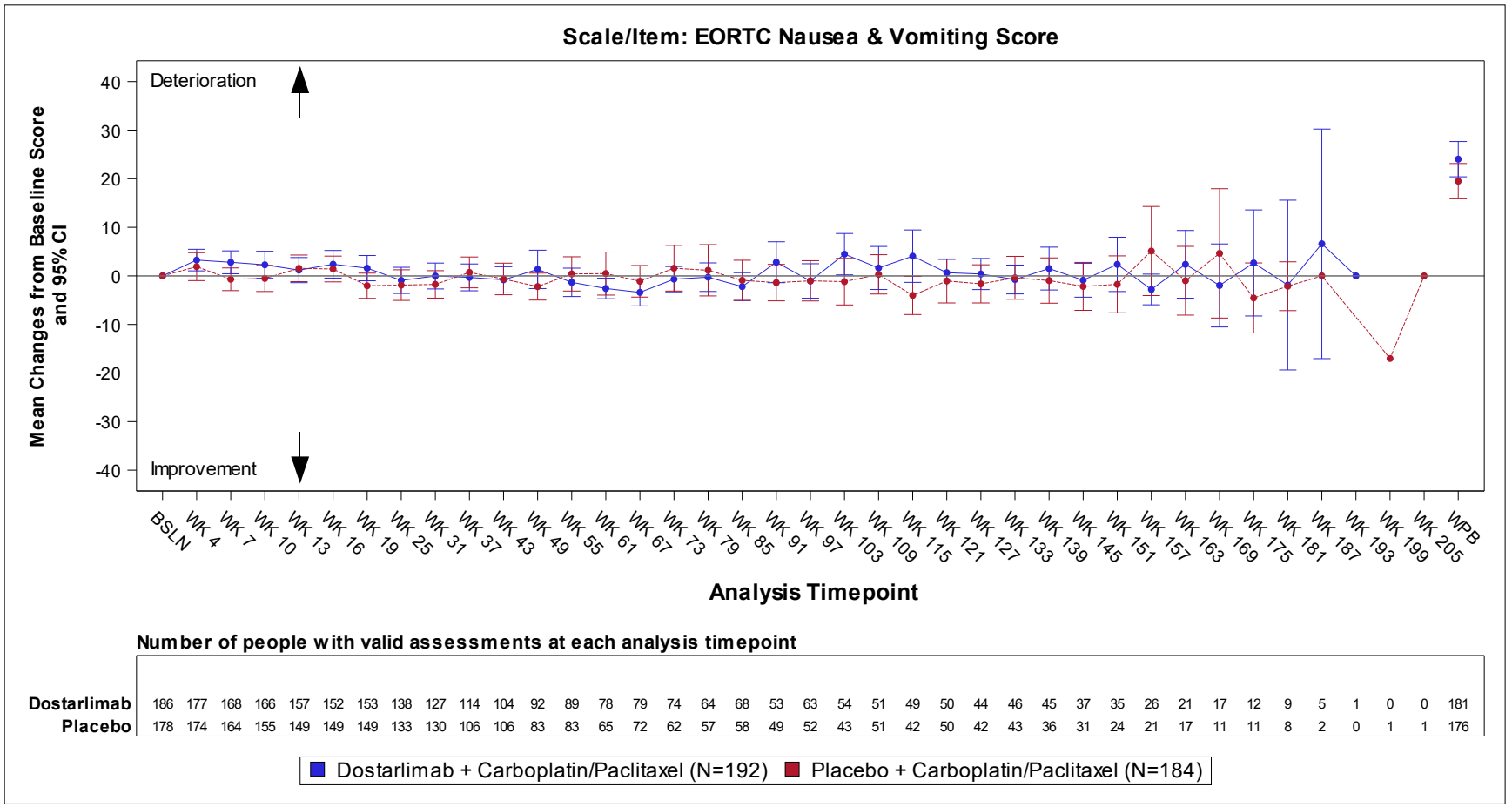
Figure 2.0902 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-C30 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_0902_q30_cfb.sas, Output: f_2_0902_q30_cfb.rtf, Generated on: 02AUG2024 07:27,
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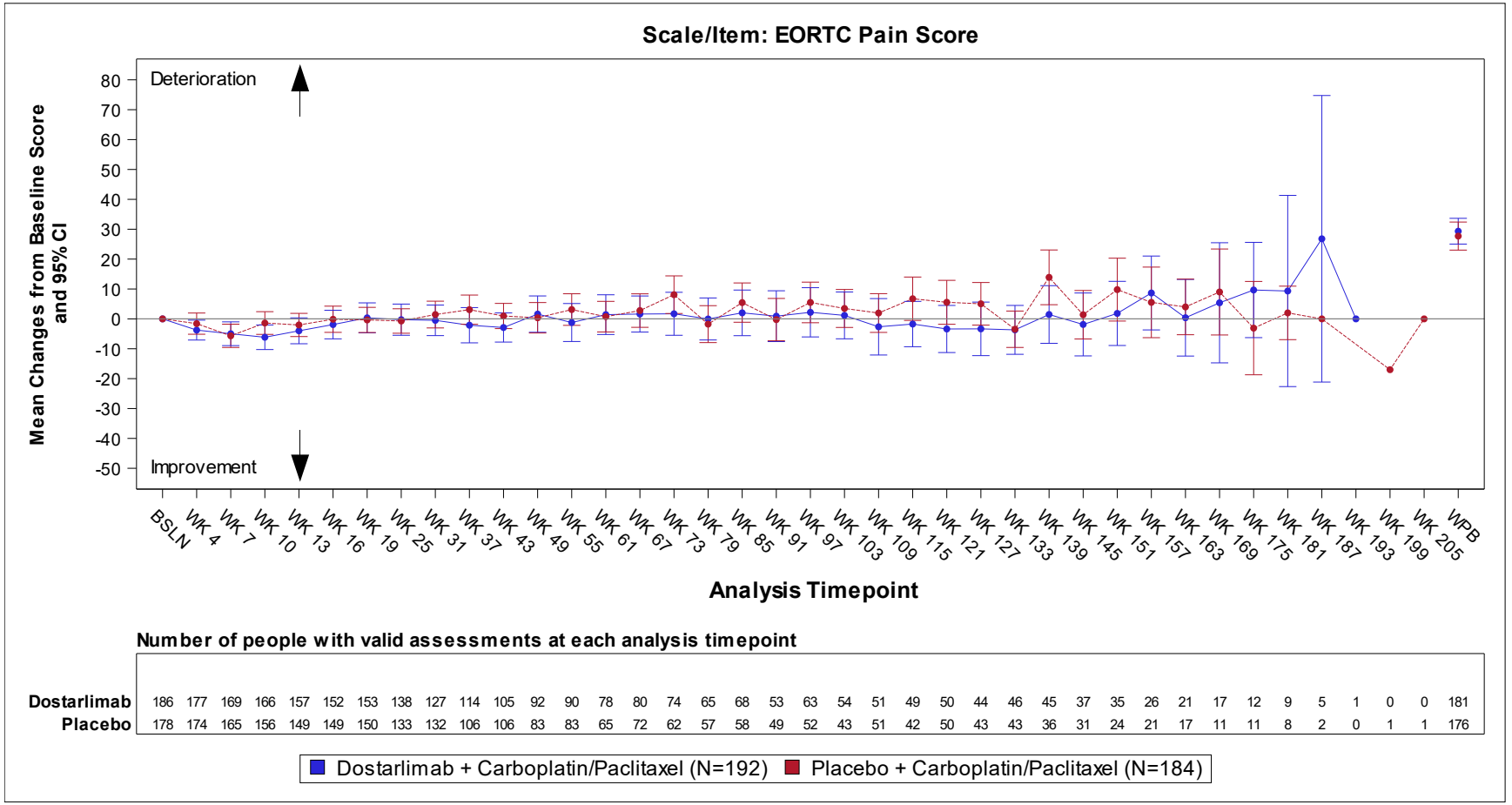

BSLN=Baseline WPB=Worst Post-Baseline
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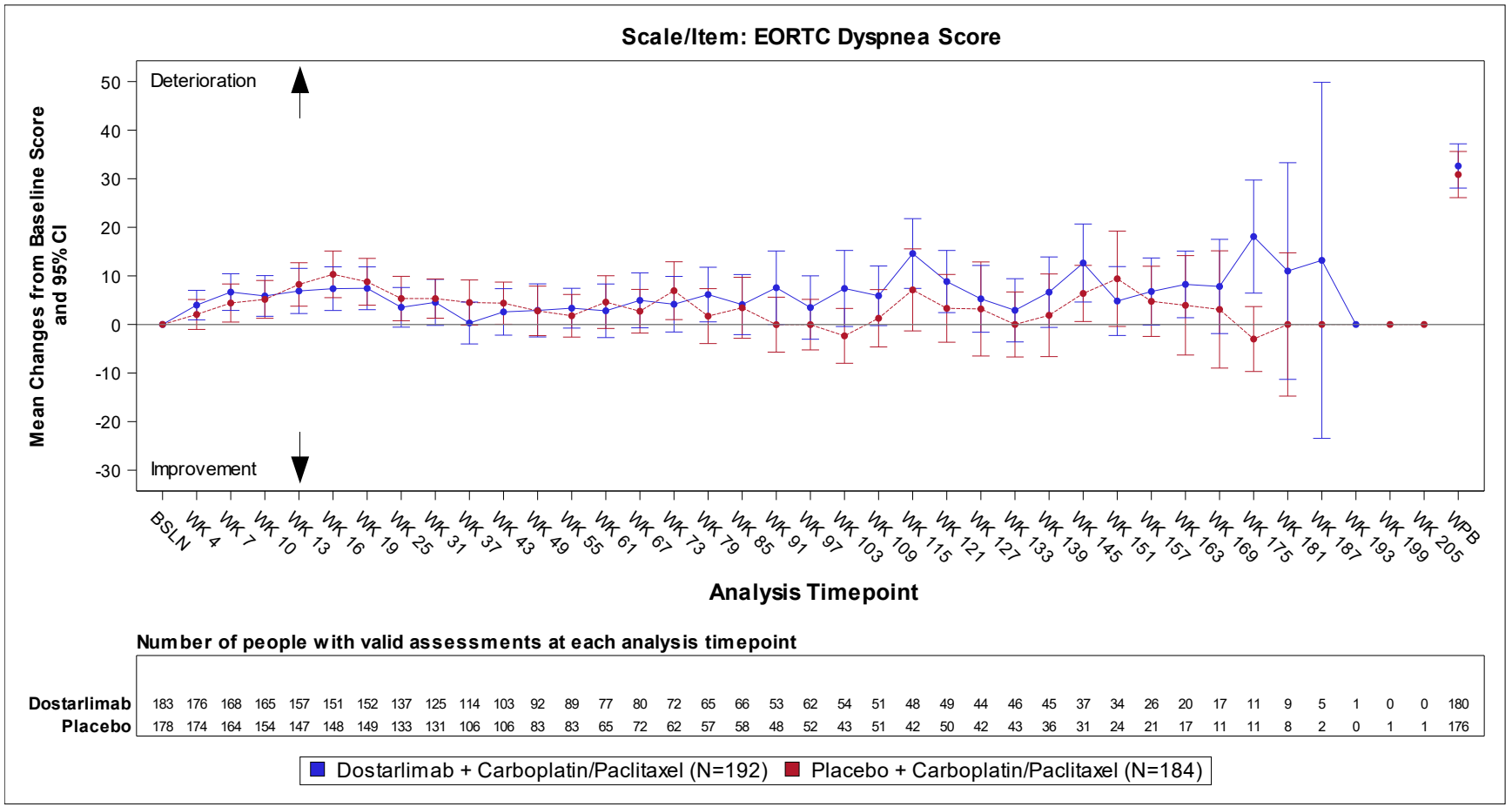
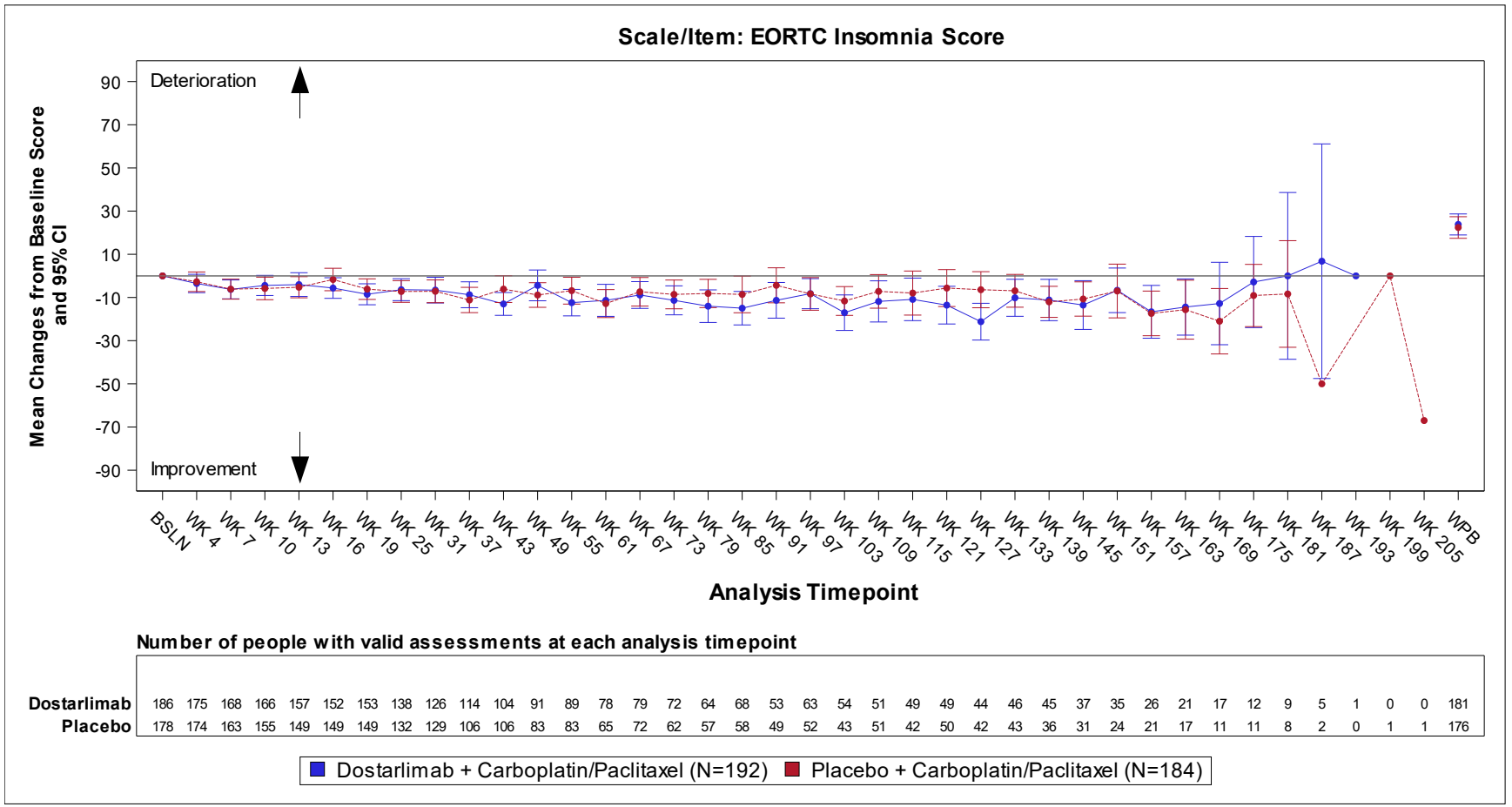
Figure 2.0902 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-C30 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_0902_q30_cfb.sas, Output: f_2_0902_q30_cfb.rtf, Generated on: 02AUG2024 07:27,
Data Cutoff Date: 22SEP2023

Figure 2.0902 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-C30 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
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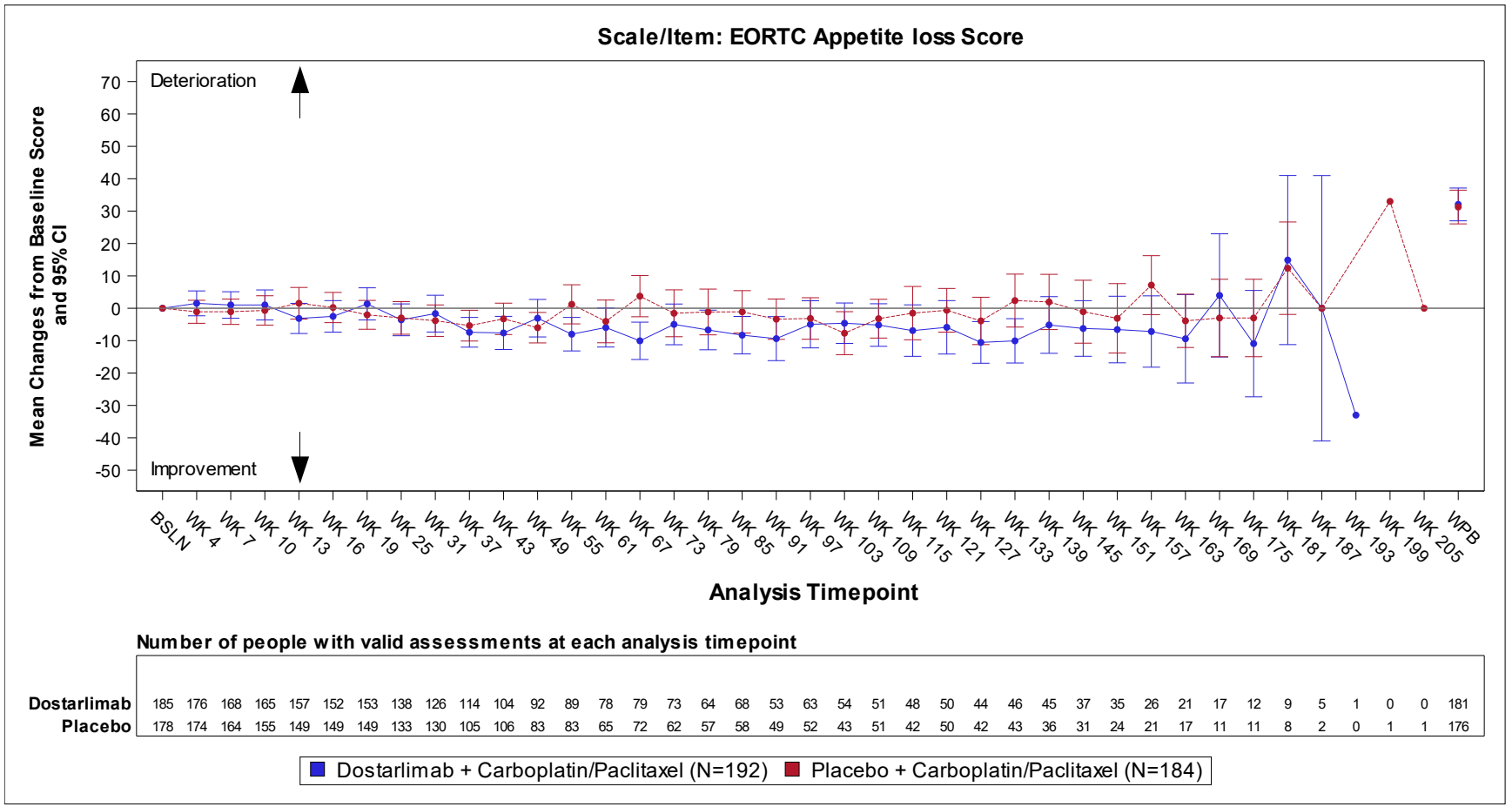
Data Cutoff Date: 22SEP2023

Figure 2.0902 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-C30 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
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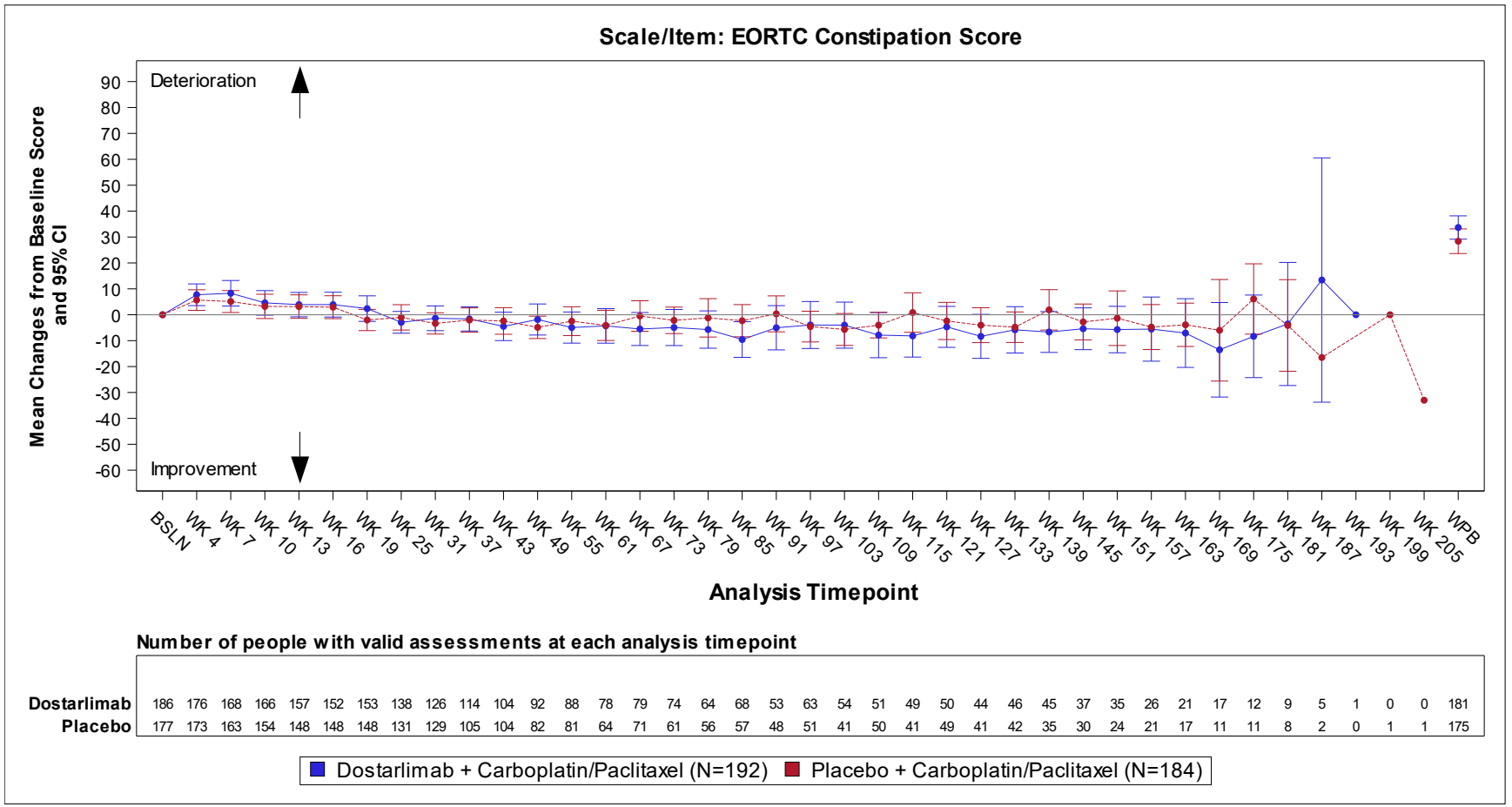
Figure 2.0902 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-C30 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
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Data Cutoff Date: 22SEP2023

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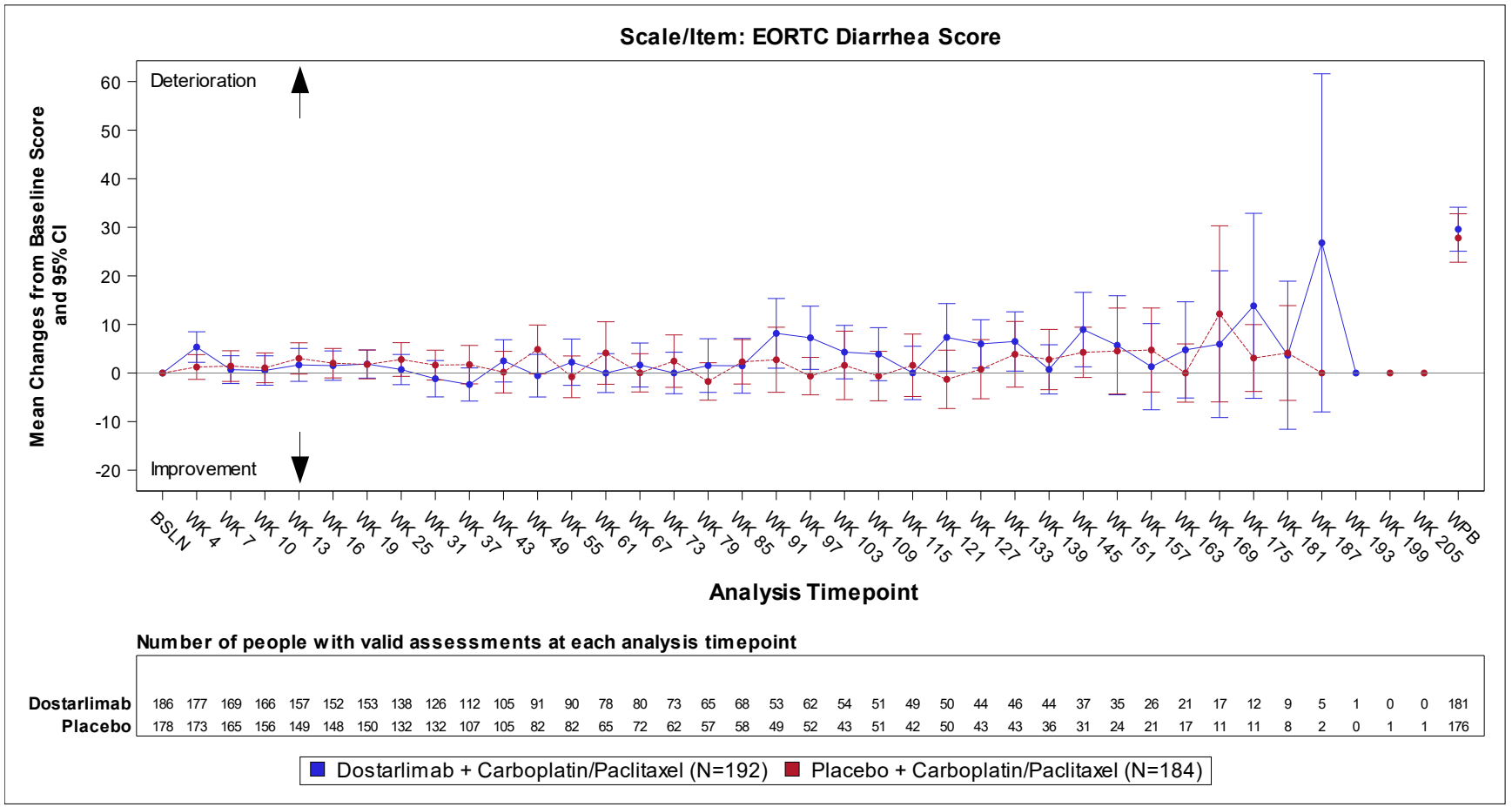

BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
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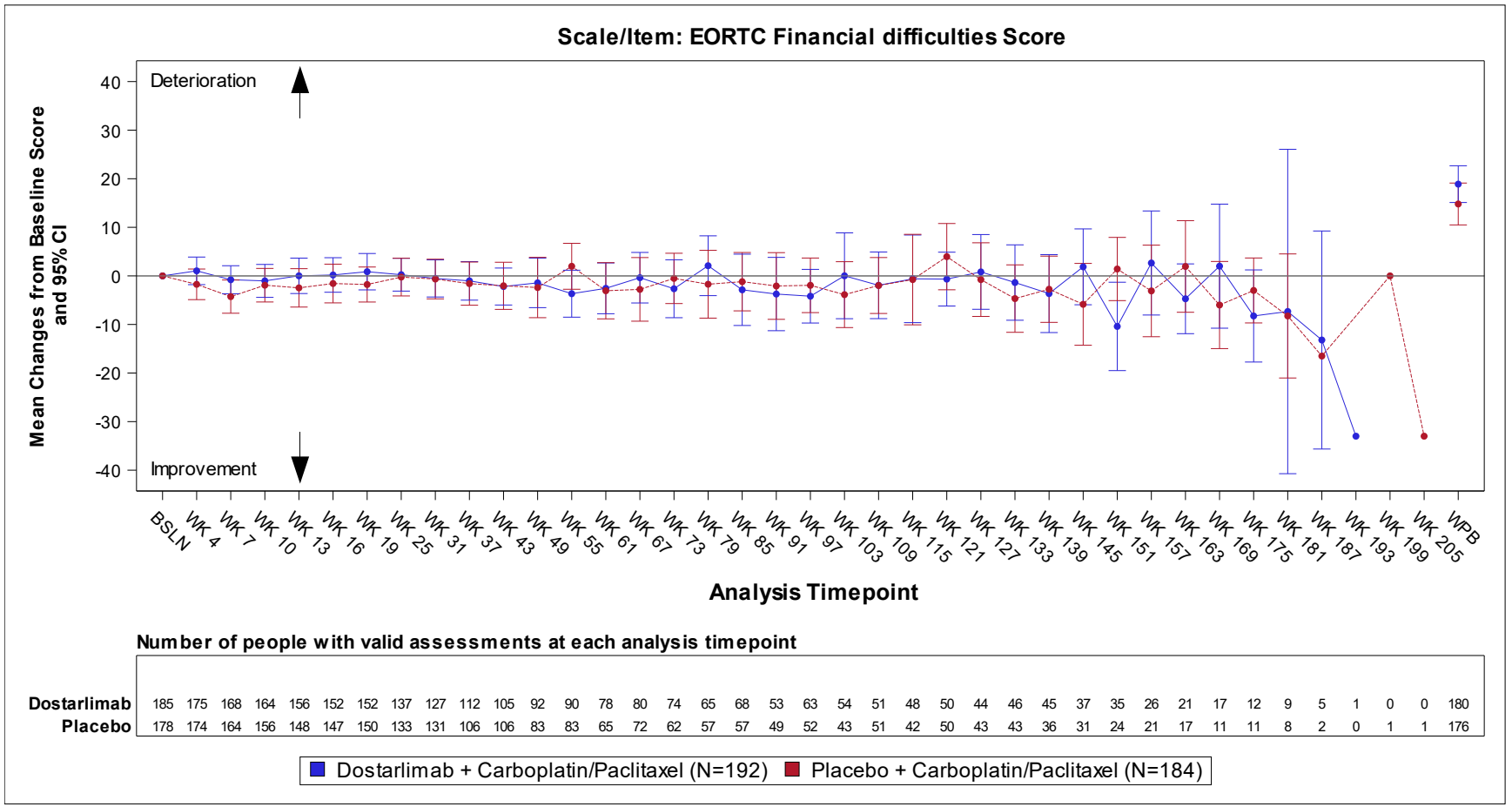
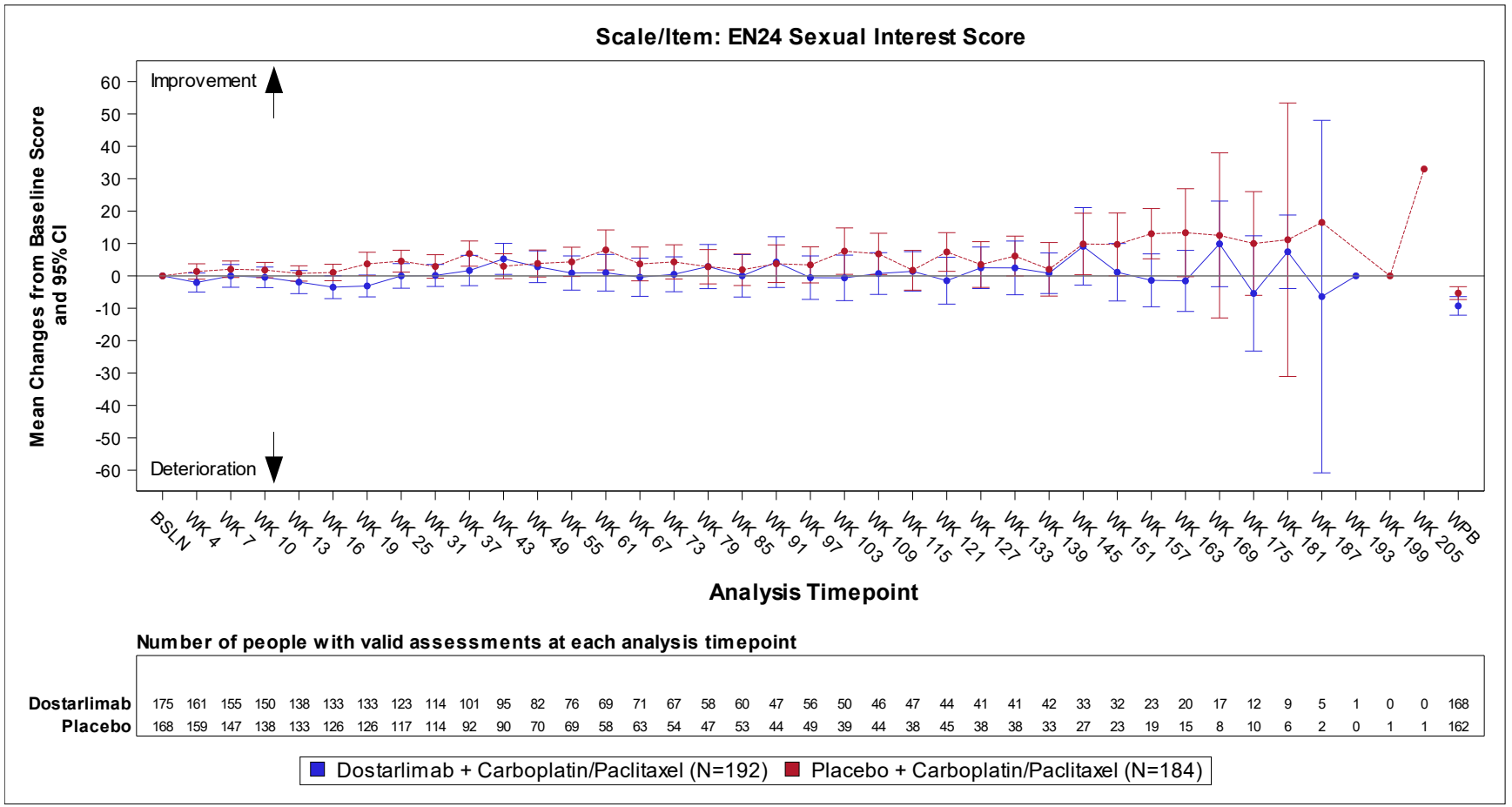


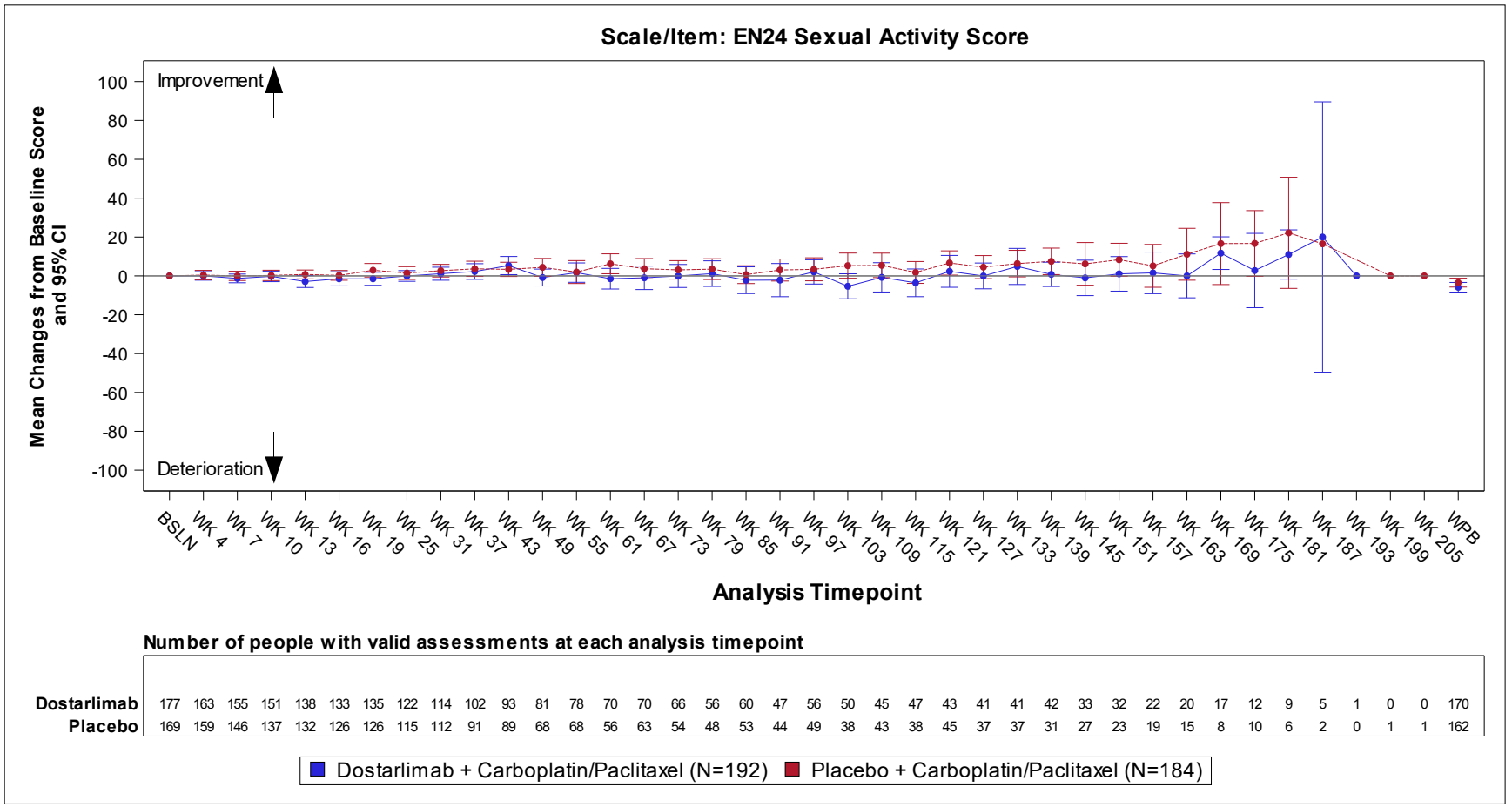
BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_0902_q30_cfb.sas, Output: f_2_0902_q30_cfb.rtf, Generated on: 02AUG2024 07:27,
Data Cutoff Date: 22SEP2023

Figure 2.1502 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-EN24 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



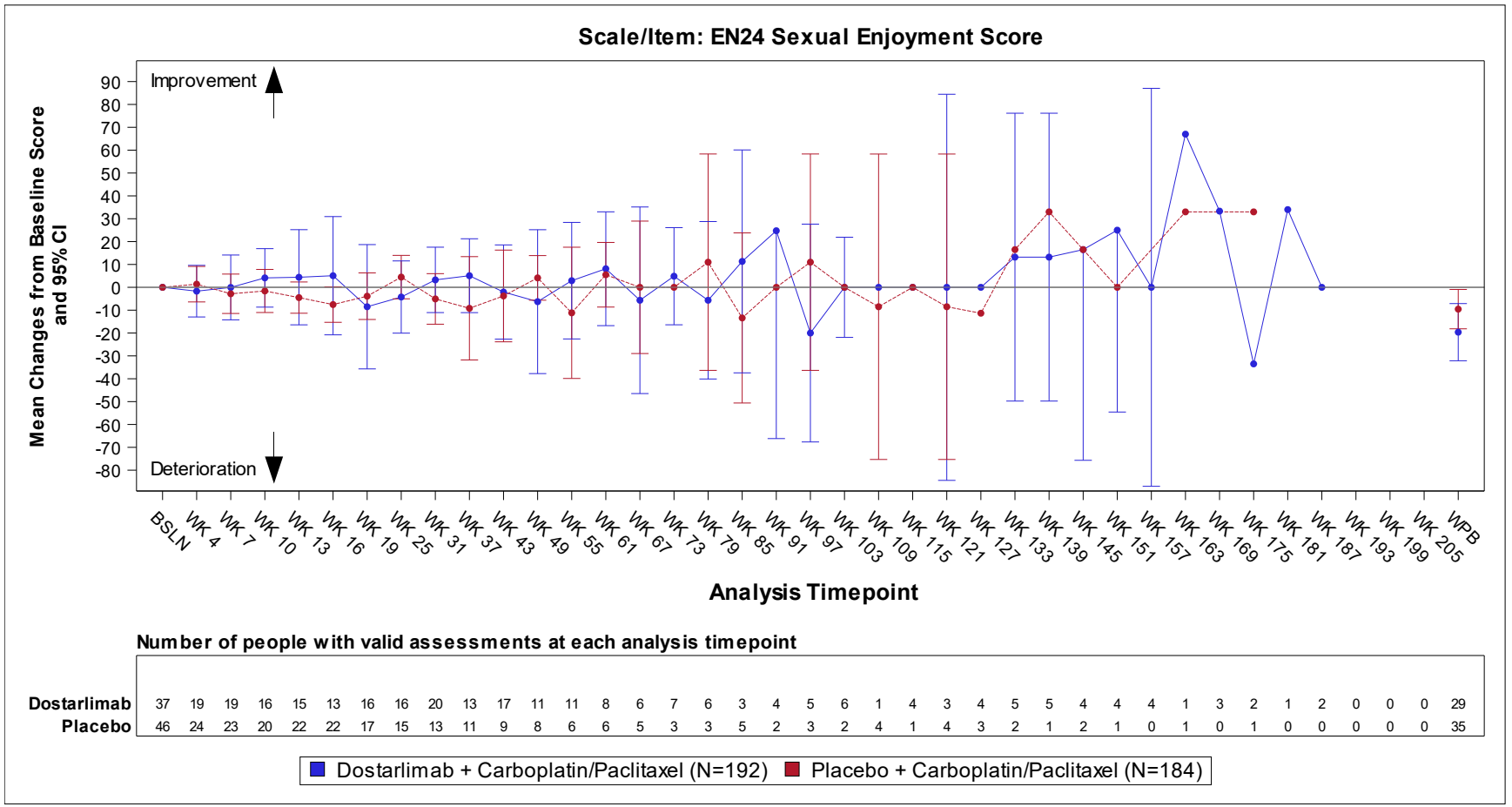
BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_1502_en24_cfb.sas, Output: f_2_1502_en24_cfb.rtf, Generated on: 02AUG2024 07:39,
Data Cutoff Date: 22SEP2023

Figure 2.1502 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-EN24 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



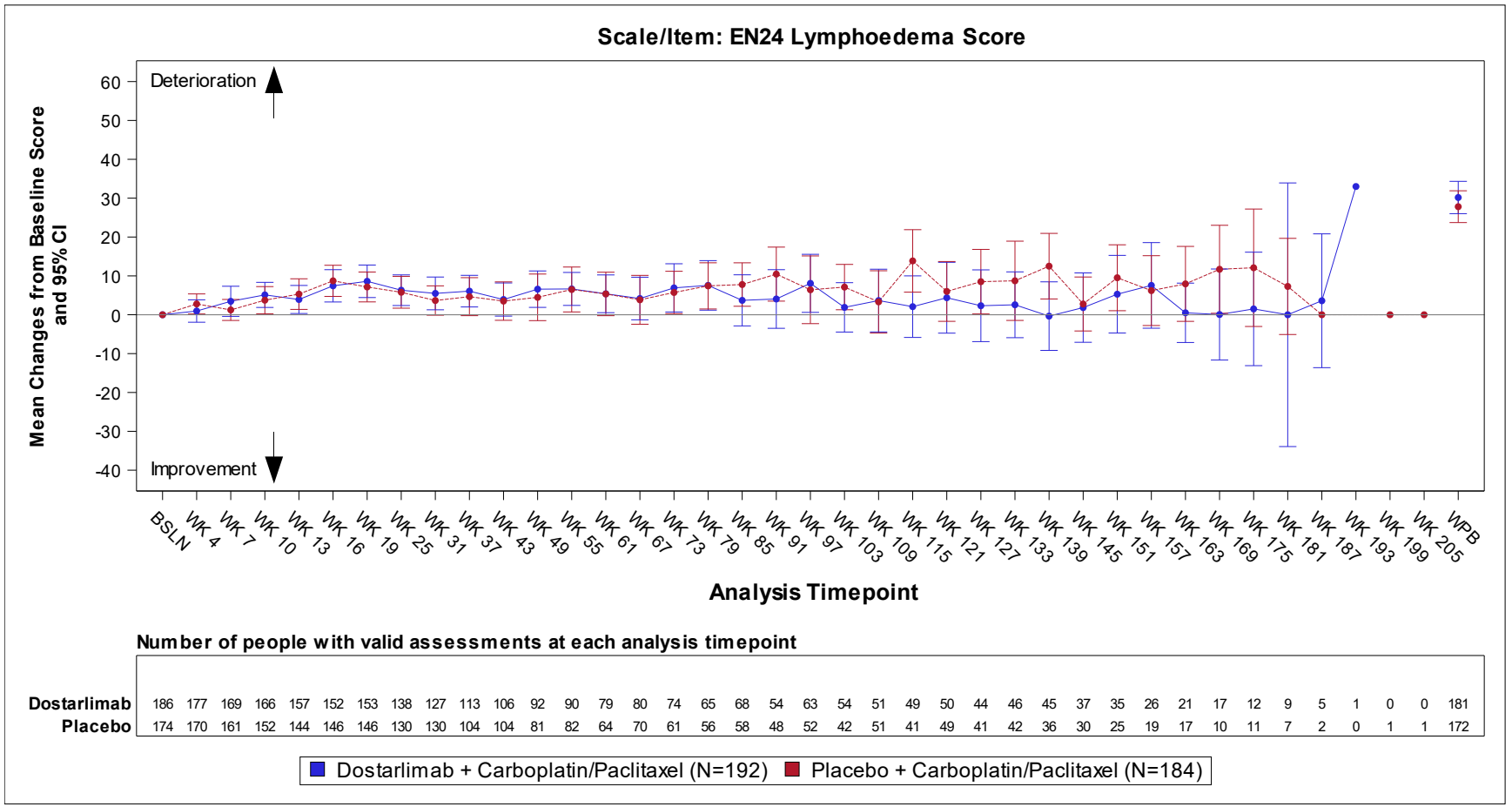
BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_1502_en24_cfb.sas, Output: f_2_1502_en24_cfb.rtf, Generated on: 02AUG2024 07:39,
Data Cutoff Date: 22SEP2023

Figure 2.1502 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-EN24 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



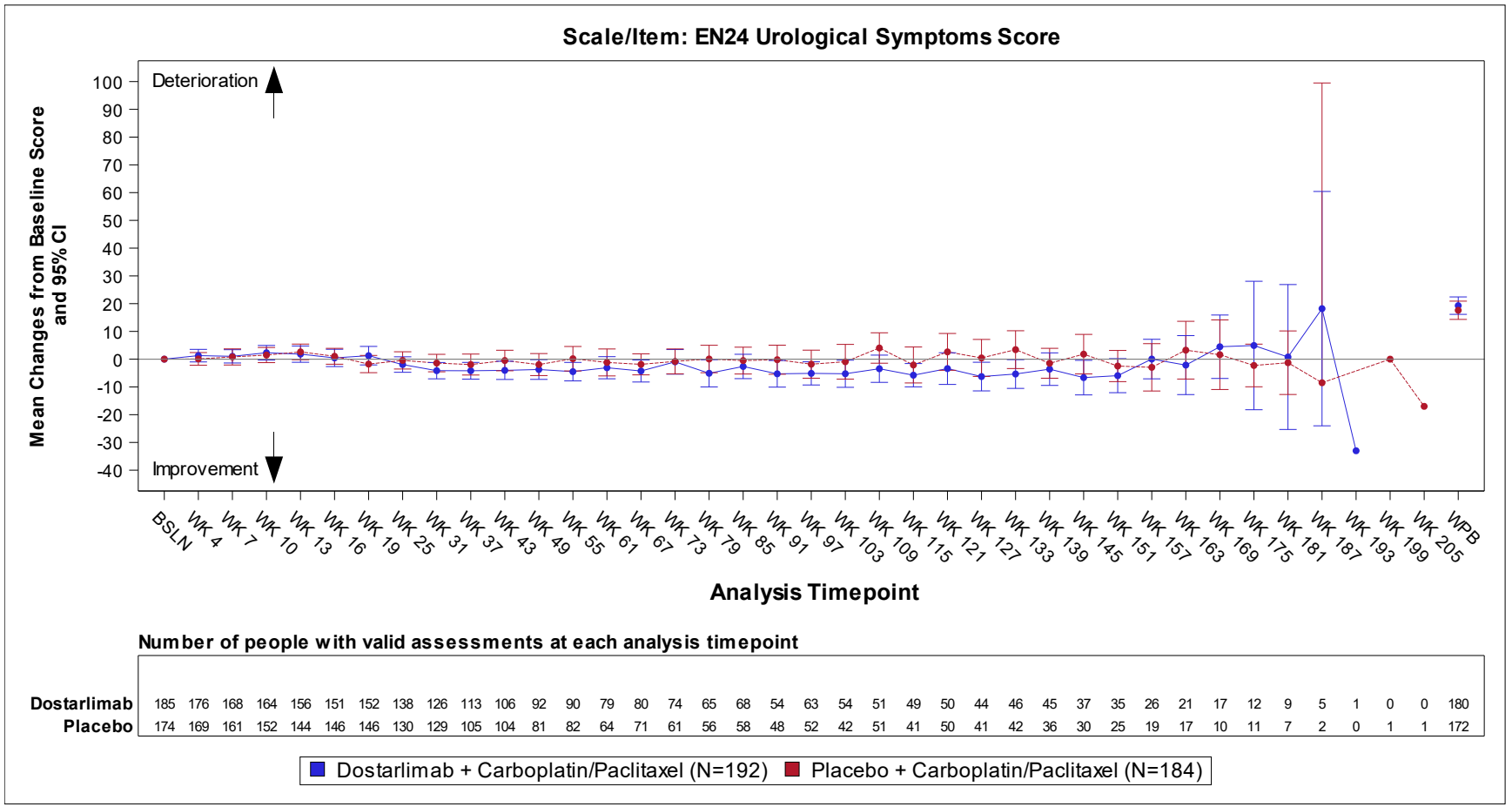
BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_1502_en24_cfb.sas, Output: f_2_1502_en24_cfb.rtf, Generated on: 02AUG2024 07:39,
Data Cutoff Date: 22SEP2023

Figure 2.1502 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-EN24 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



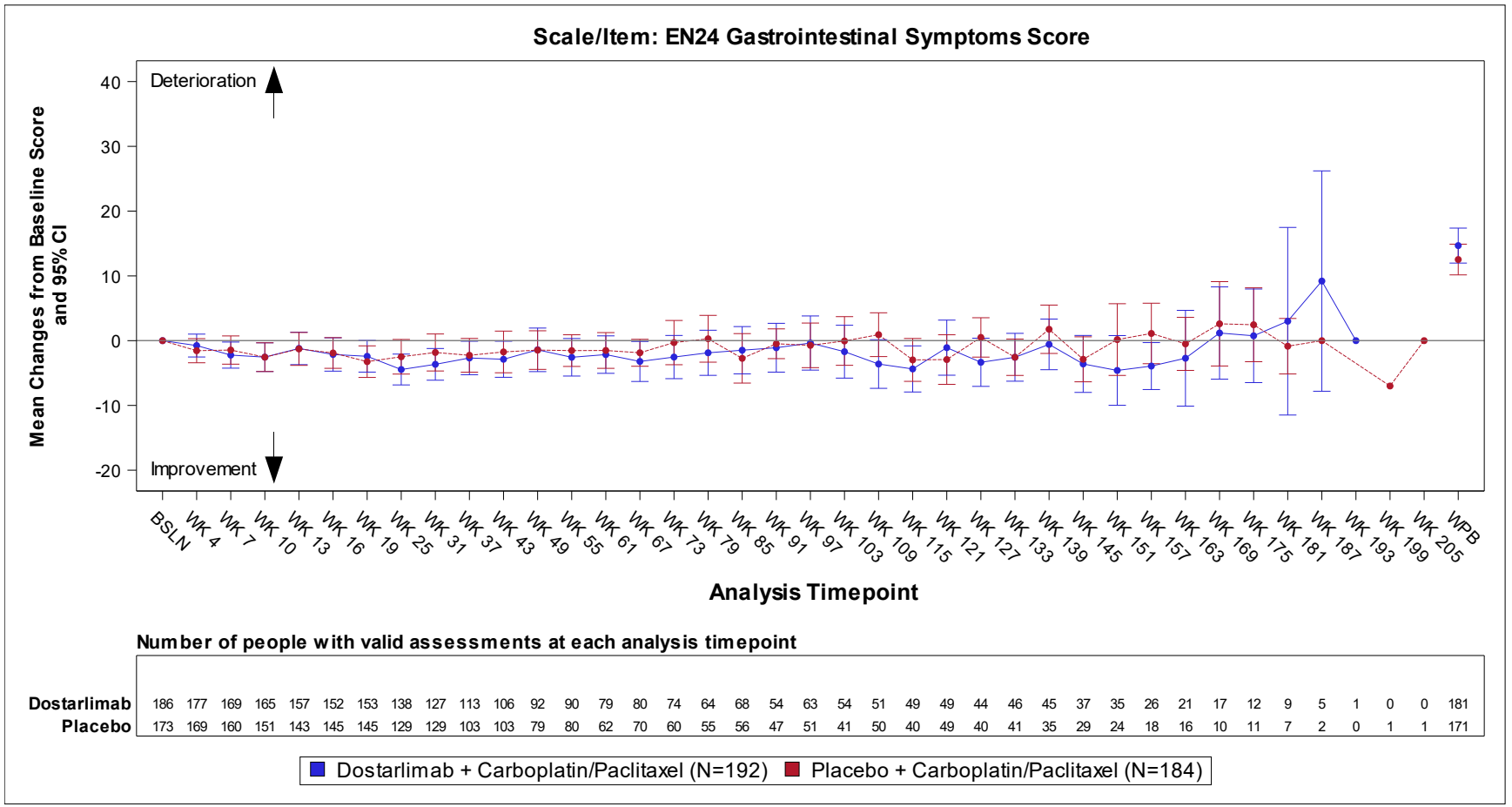
BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_1502_en24_cfb.sas, Output: f_2_1502_en24_cfb.rtf, Generated on: 02AUG2024 07:39,
Data Cutoff Date: 22SEP2023

Figure 2.1502 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-EN24 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



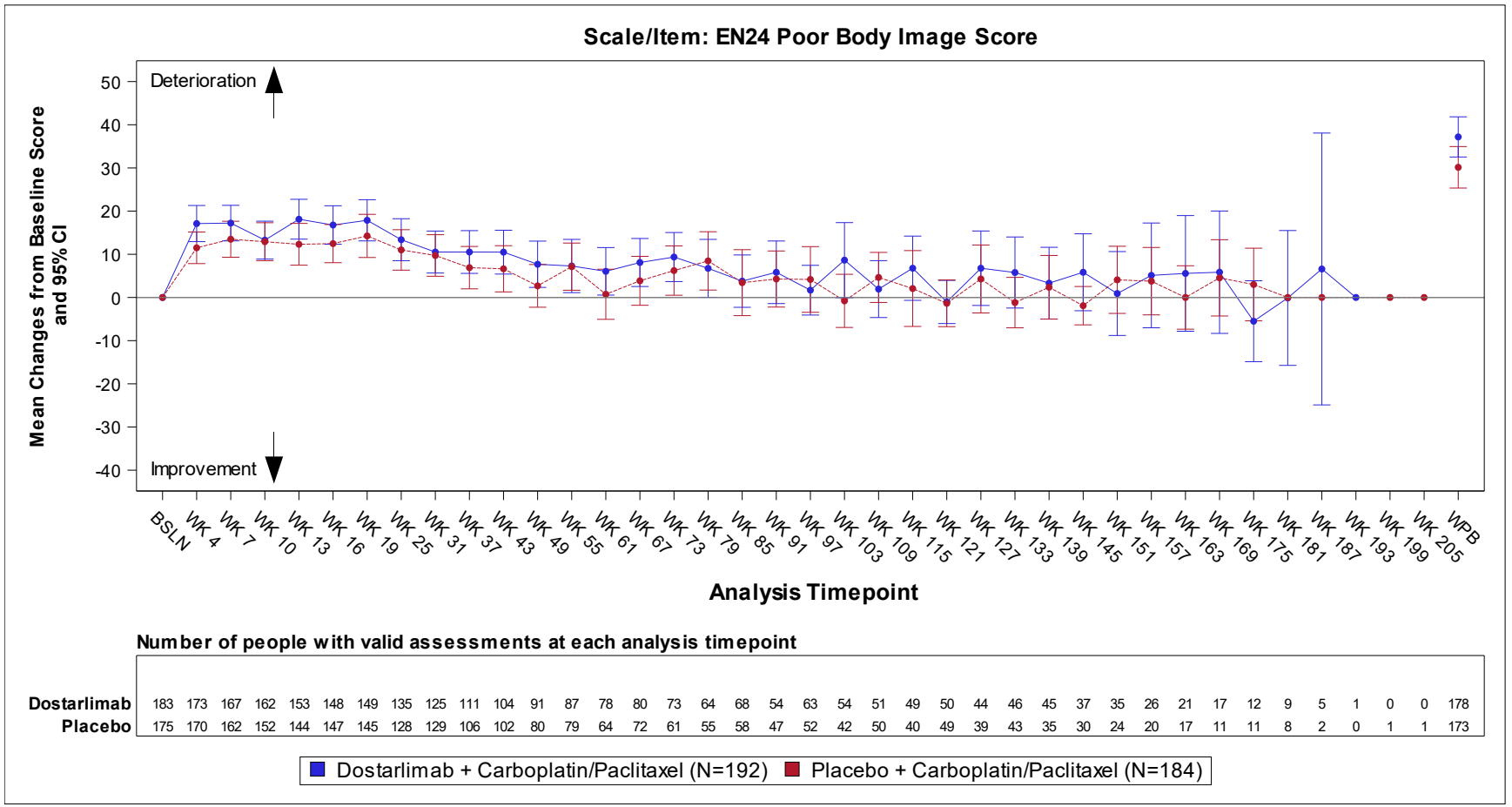
BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_1502_en24_cfb.sas, Output: f_2_1502_en24_cfb.rtf, Generated on: 02AUG2024 07:39,
Data Cutoff Date: 22SEP2023

Figure 2.1502 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-EN24 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



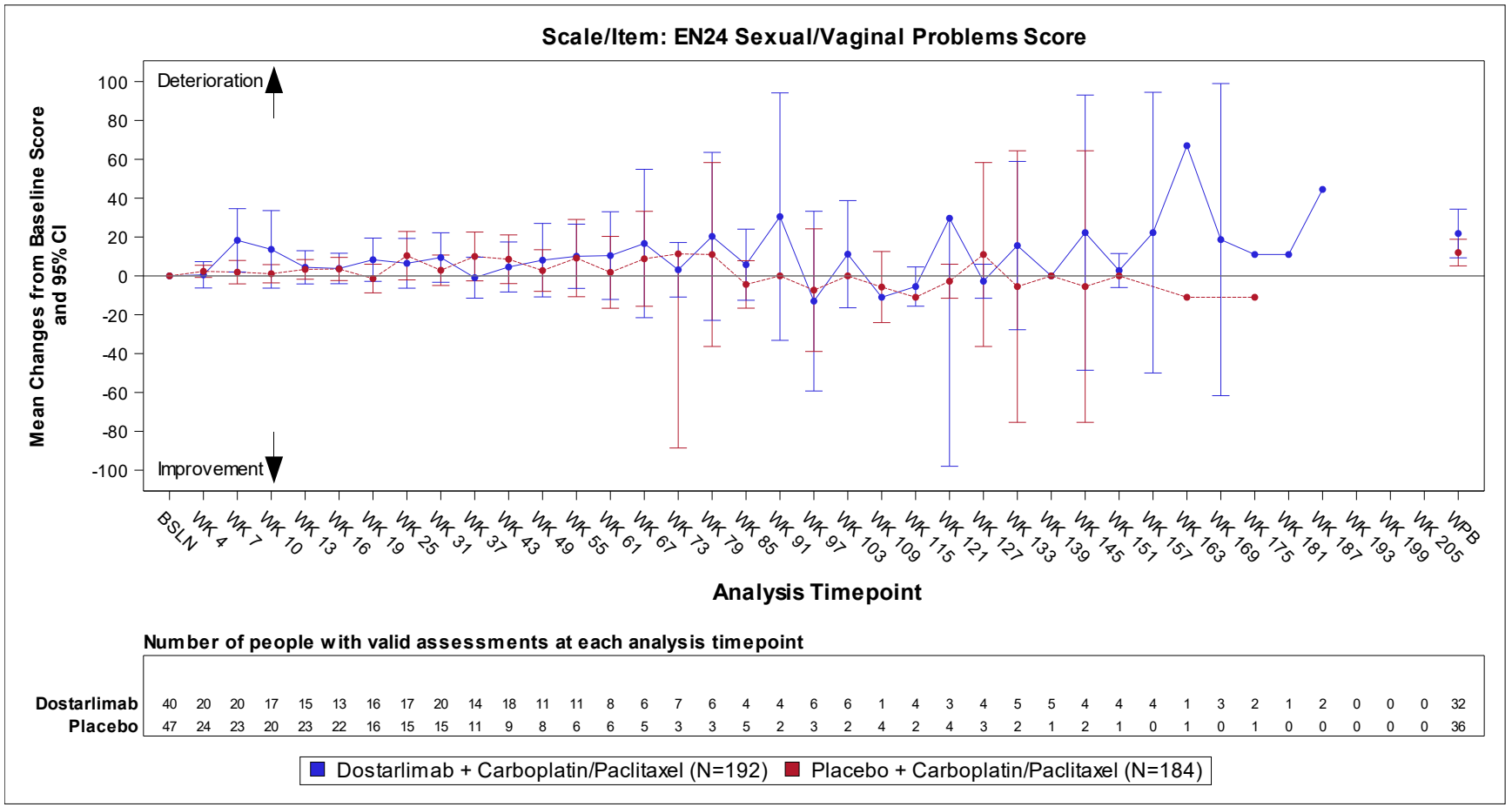
BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_1502_en24_cfb.sas, Output: f_2_1502_en24_cfb.rtf, Generated on: 02AUG2024 07:39,
Data Cutoff Date: 22SEP2023

Figure 2.1502 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-EN24 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



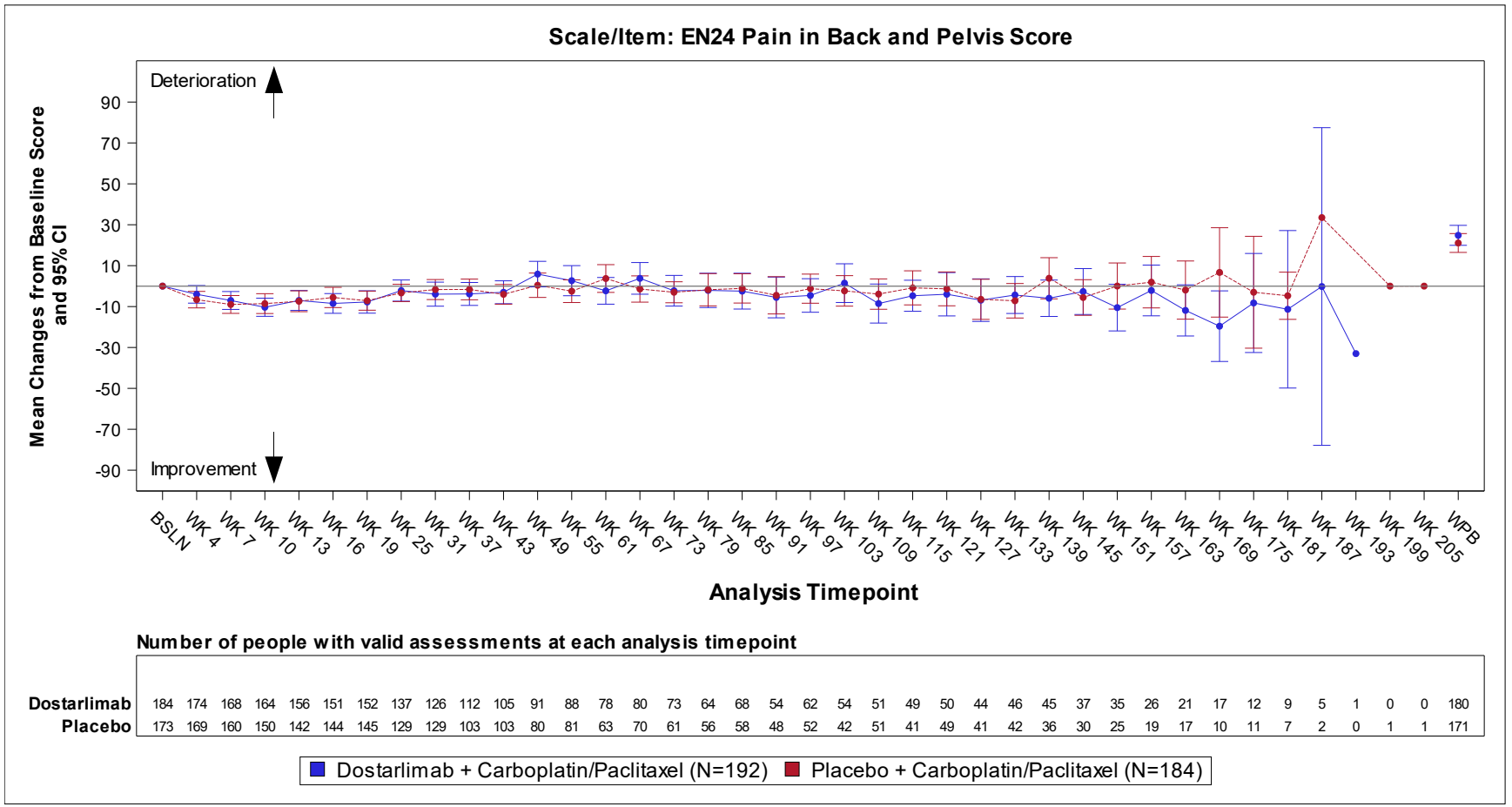
BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_1502_en24_cfb.sas, Output: f_2_1502_en24_cfb.rtf, Generated on: 02AUG2024 07:39,
Data Cutoff Date: 22SEP2023

Figure 2.1502 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-EN24 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



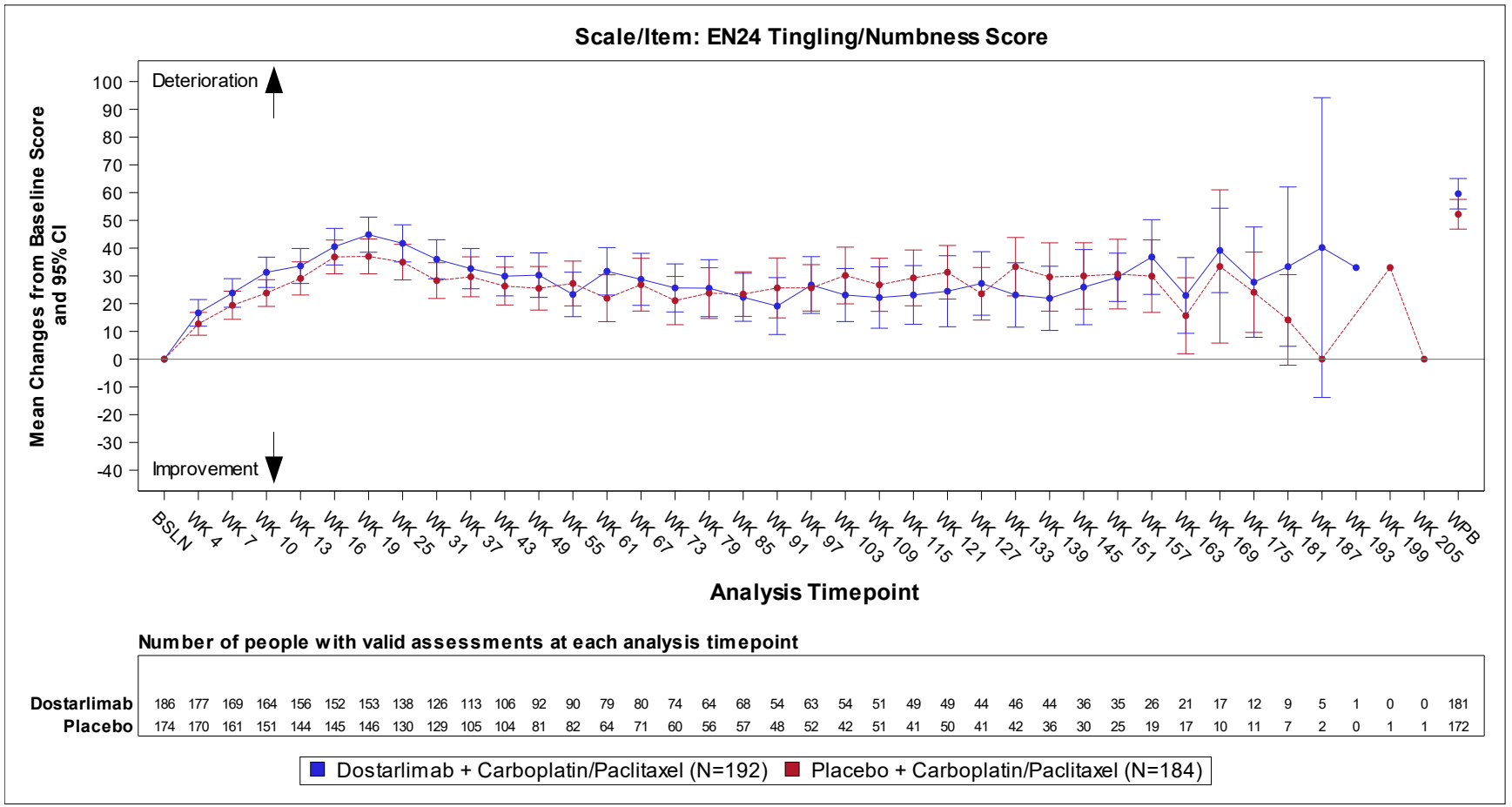
BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_1502_en24_cfb.sas, Output: f_2_1502_en24_cfb.rtf, Generated on: 02AUG2024 07:39,
Data Cutoff Date: 22SEP2023

Figure 2.1502 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-EN24 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



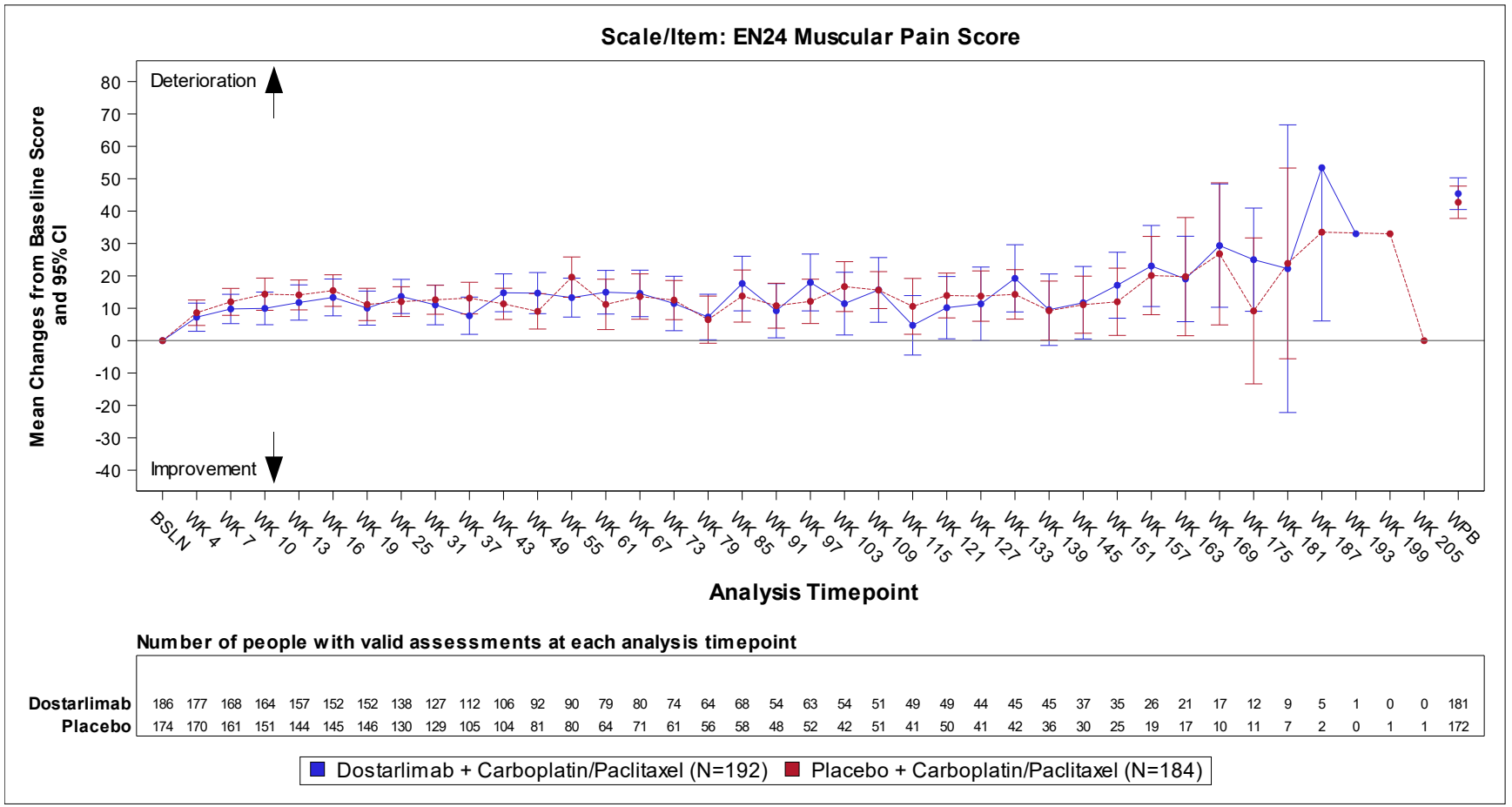
BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_1502_en24_cfb.sas, Output: f_2_1502_en24_cfb.rtf, Generated on: 02AUG2024 07:39,
Data Cutoff Date: 22SEP2023

Figure 2.1502 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-EN24 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



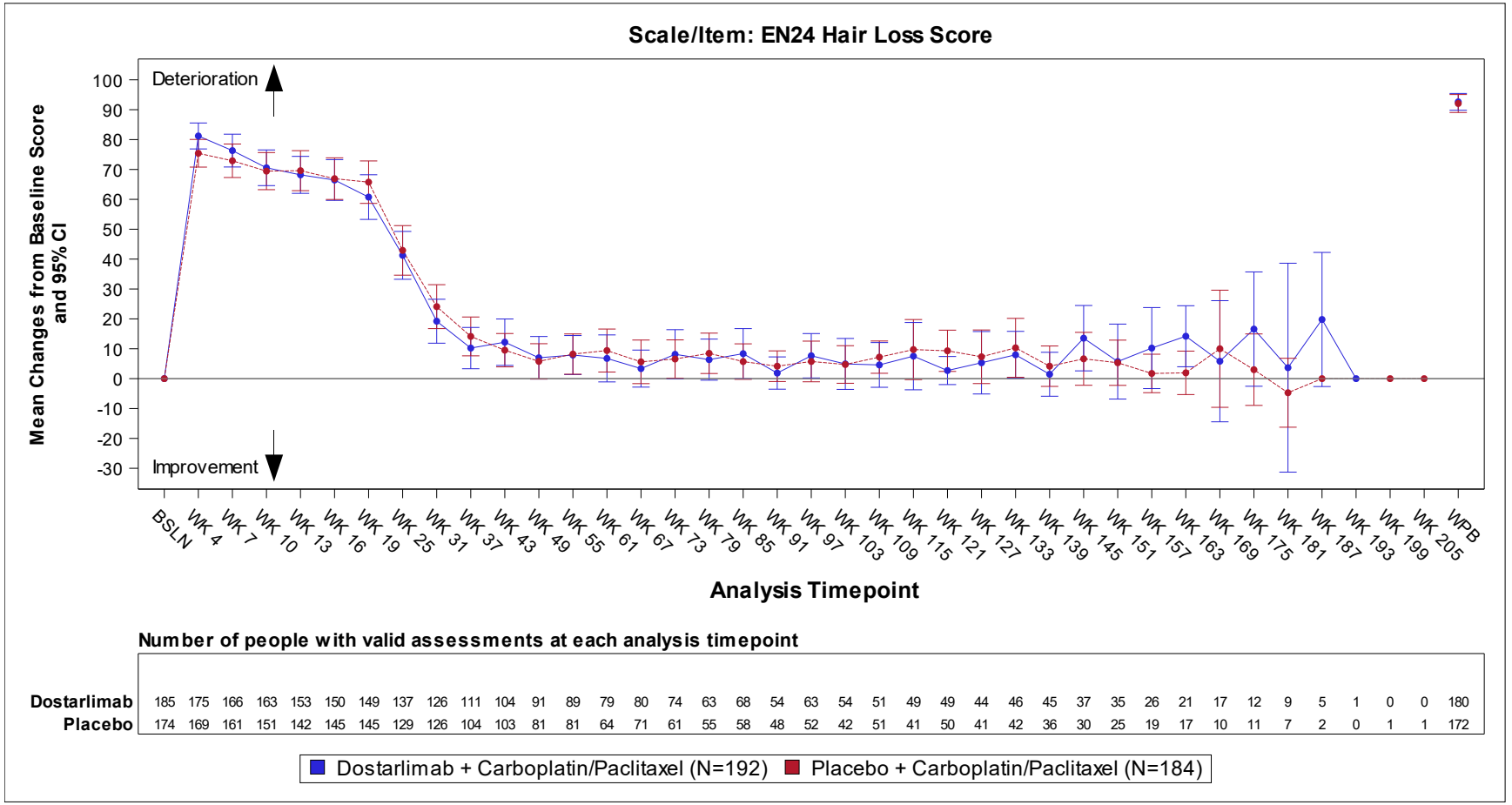
BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_1502_en24_cfb.sas, Output: f_2_1502_en24_cfb.rtf, Generated on: 02AUG2024 07:39,
Data Cutoff Date: 22SEP2023

Figure 2.1502 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-EN24 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



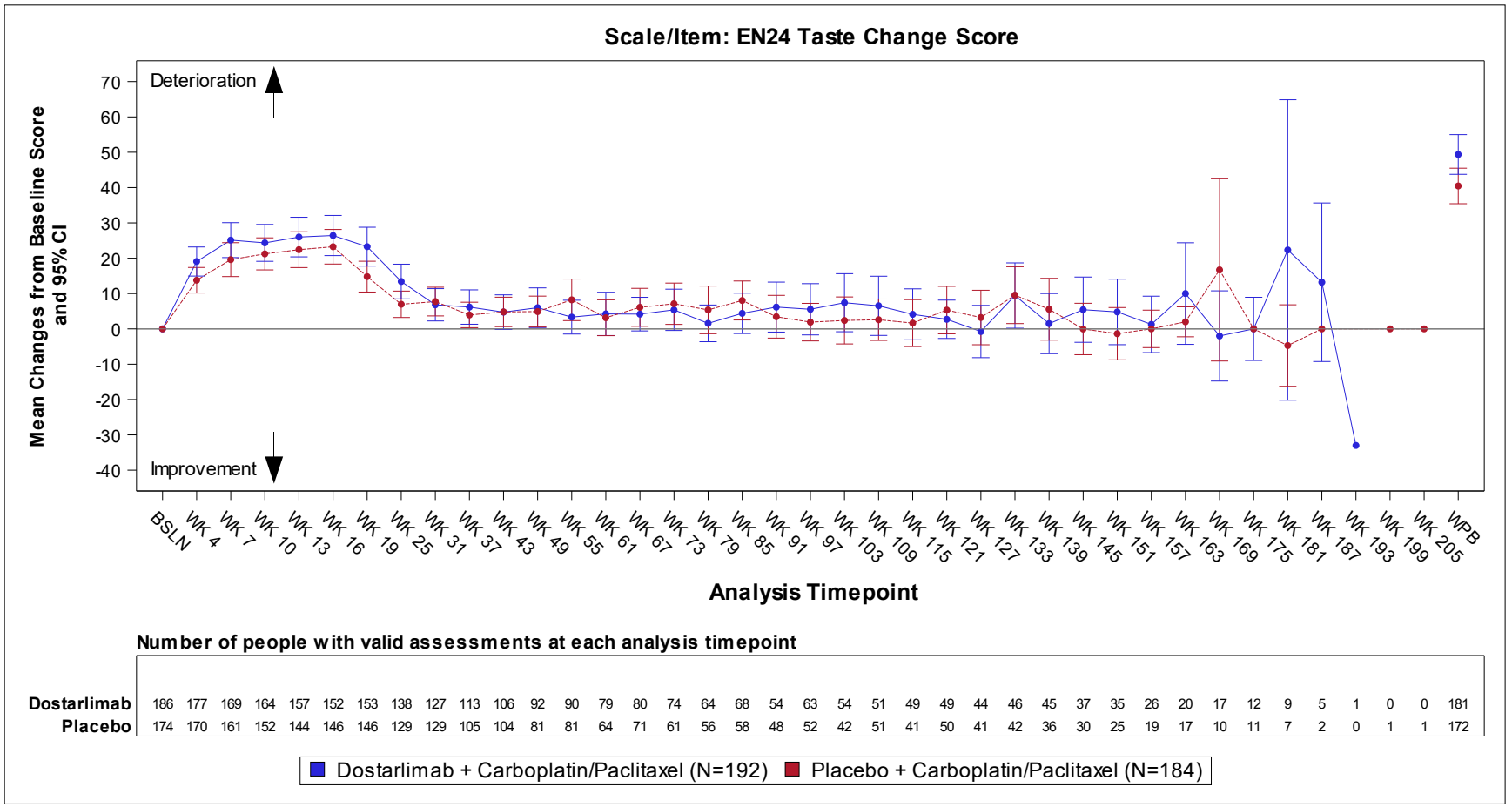
BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_1502_en24_cfb.sas, Output: f_2_1502_en24_cfb.rtf, Generated on: 02AUG2024 07:39,
Data Cutoff Date: 22SEP2023

Figure 2.1502 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-EN24 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



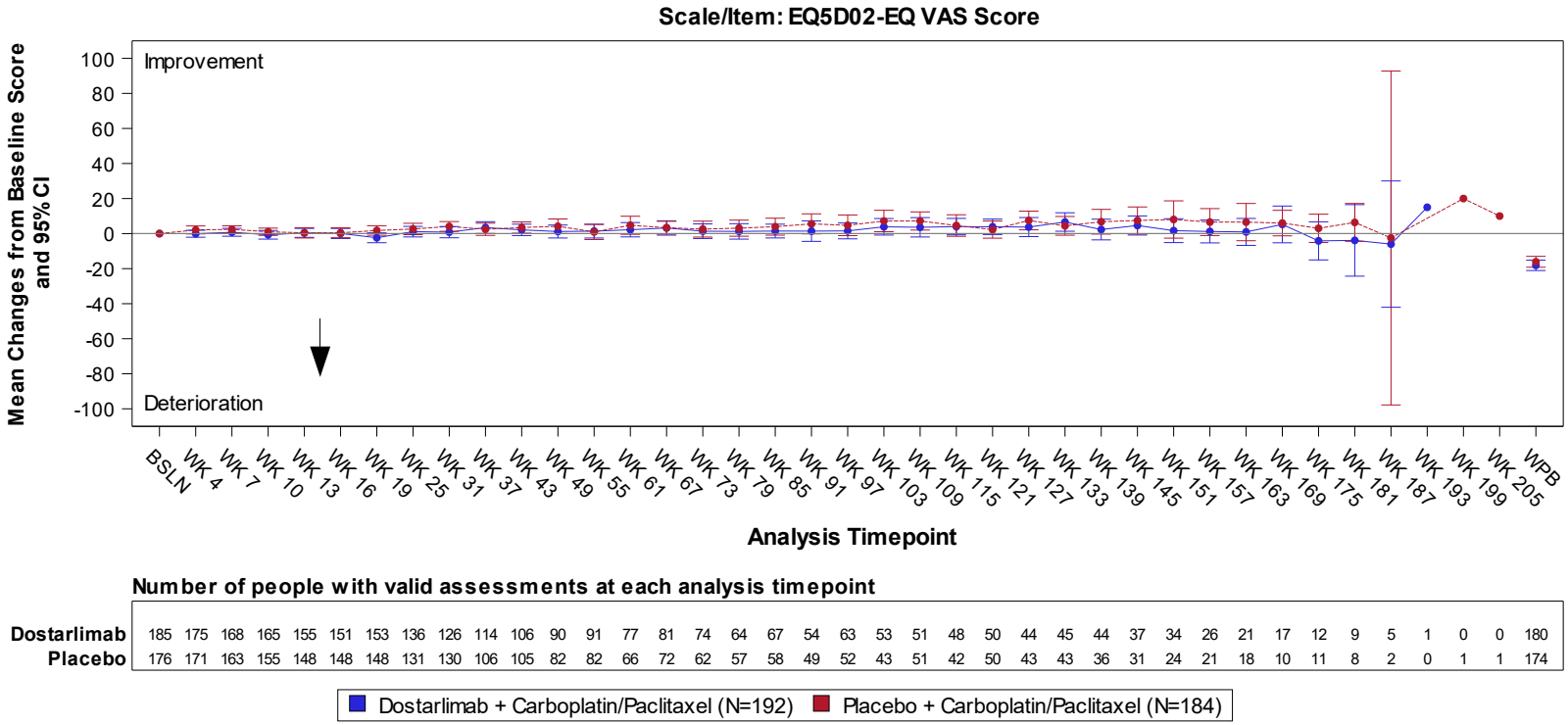
BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_1502_en24_cfb.sas, Output: f_2_1502_en24_cfb.rtf, Generated on: 02AUG2024 07:39,
Data Cutoff Date: 22SEP2023

Figure 2.1502 Plot of Change from Baseline and Confidence Interval of EORTC-QLQ-EN24 Domain Scores (ITT Analysis Set): MMRp/MSS Subjects



BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_1502_en24_cfb.sas, Output: f_2_1502_en24_cfb.rtf, Generated on: 02AUG2024 07:39,
Data Cutoff Date: 22SEP2023

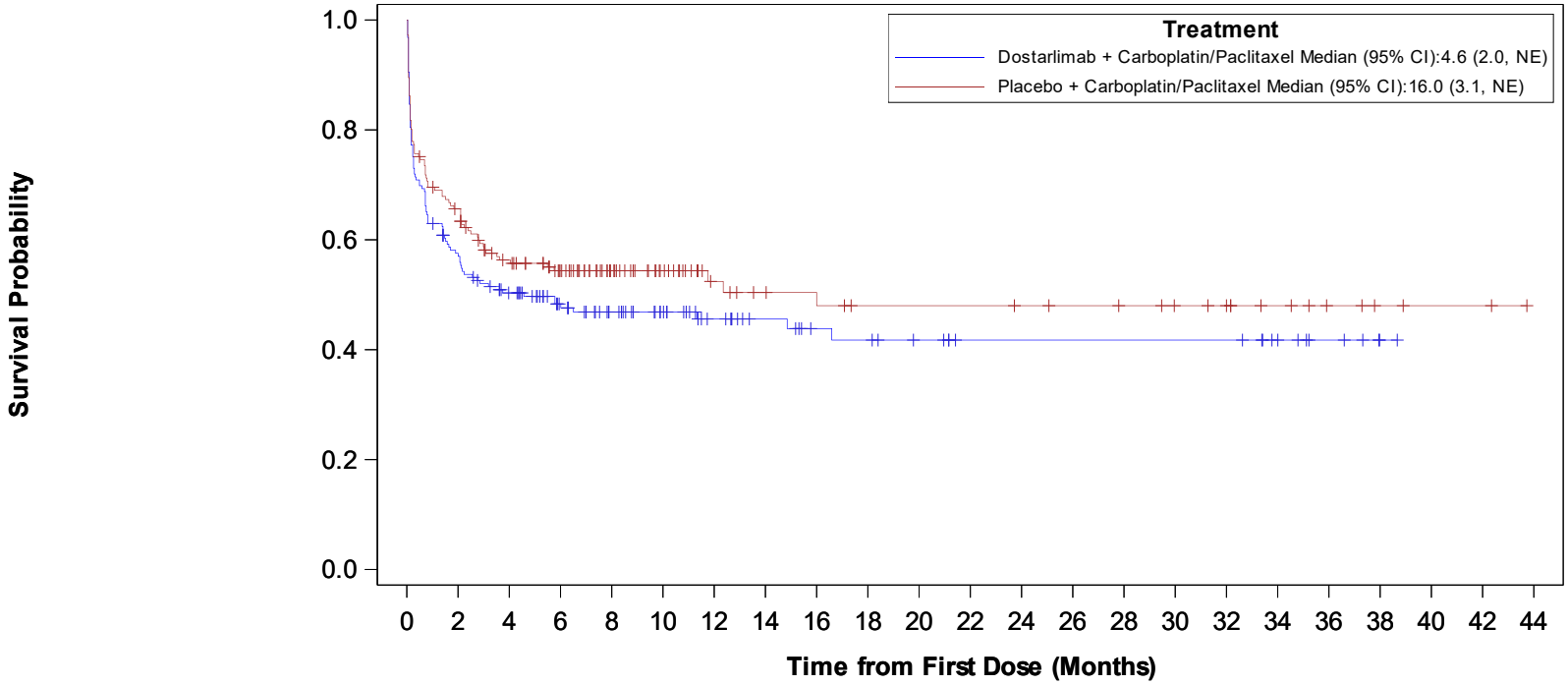
Figure 2.2102 Plot of Change from Baseline and Confidence Interval of EQ-5D-5L Visual Analogue Scores (ITT Analysis Set): MMRp/MSS Subjects



BSLN=Baseline WPB=Worst Post-Baseline
Confidence intervals which fall outside the range of [-100, 100] are not presented.
Program: f_2_2102_eq5d_cfb.sas, Output: f_2_2102_eq5d_cfb.rtf, Generated on: 30AUG2024 17:59,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Gastrointestinal disorders
Preferred Term: Nausea



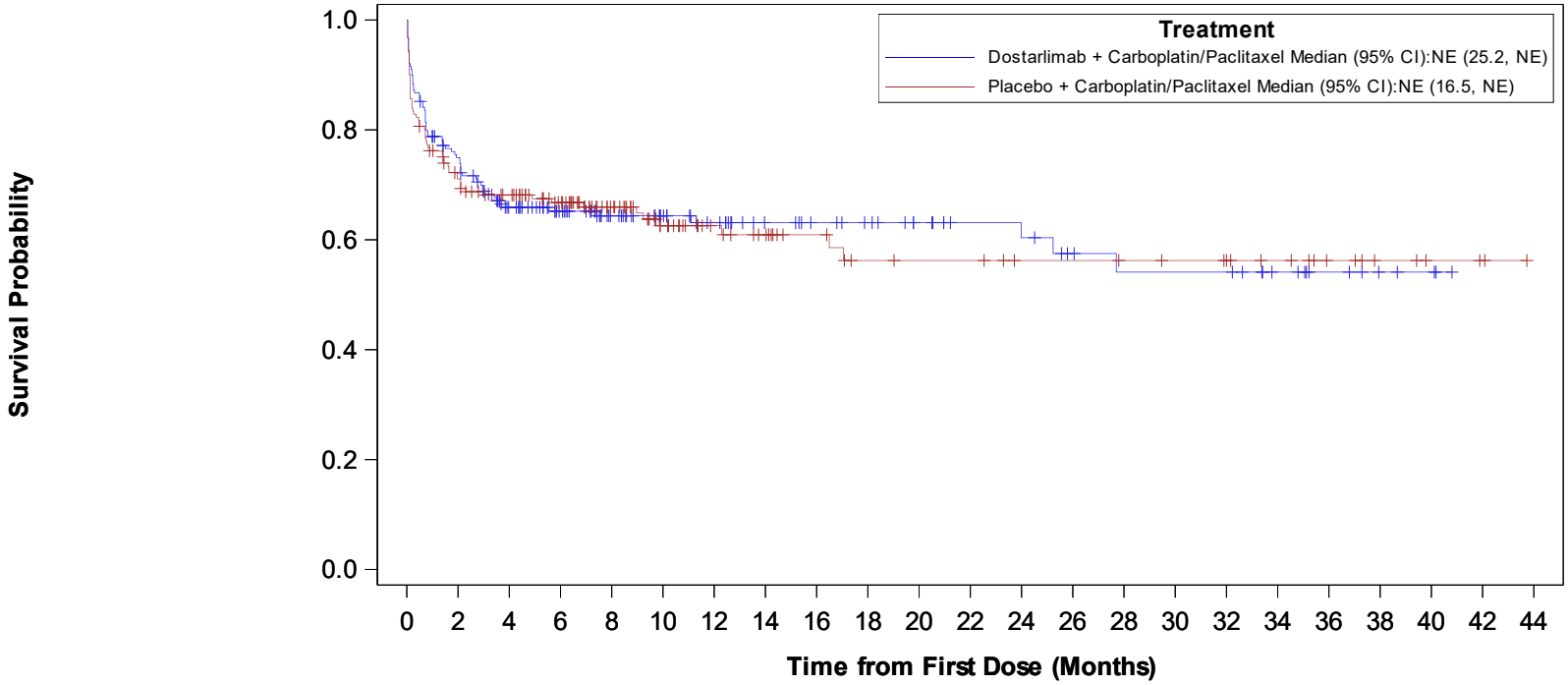
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	105(80)	85(93)	67(96)	54(98)	44(98)	33(99)	26(99)	21(100)	20(101)	17(101)	13(101)	13(101)	13(101)	13(101)	13(101)	13(101)	9(101)	5(101)	1(101)	0(101)		
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	116(62)	92(78)	75(81)	55(81)	41(81)	26(82)	22(83)	21(84)	18(84)	18(84)	18(84)	17(84)	16(84)	15(84)	13(84)	12(84)	8(84)	5(84)	3(84)	2(84)	2(84)	0(84)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Gastrointestinal disorders
Preferred Term: Constipation



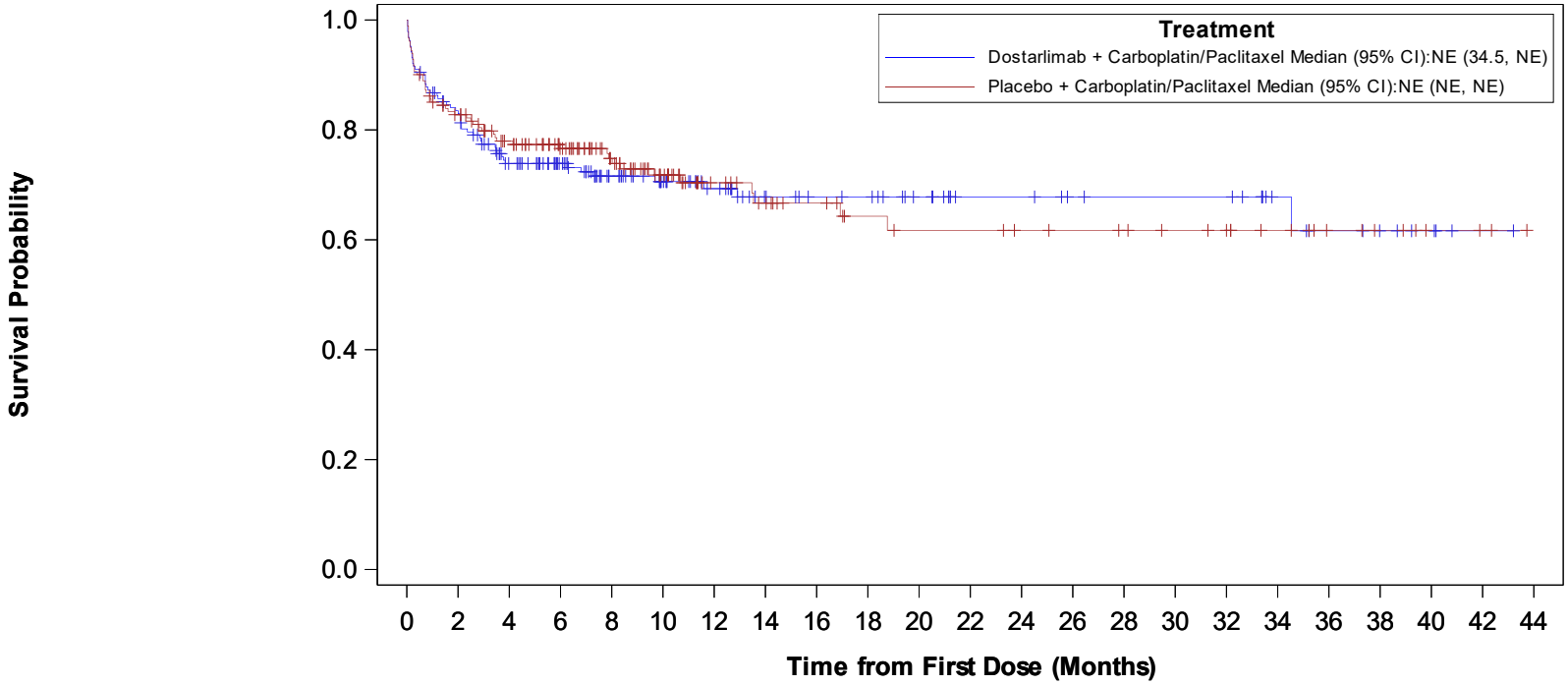
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	136(47)	106(63)	88(64)	70(65)	57(65)	49(66)	40(66)	36(66)	33(66)	28(66)	23(66)	22(67)	18(68)	16(69)	16(69)	16(69)	11(69)	7(69)	4(69)	3(69)	0(69)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	123(52)	110(57)	93(59)	69(60)	50(63)	38(63)	33(64)	27(64)	22(66)	21(66)	21(66)	18(66)	18(66)	17(66)	16(66)	15(66)	12(66)	8(66)	5(66)	3(66)	2(66)	0(66)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Gastrointestinal disorders
Preferred Term: Diarrhoea



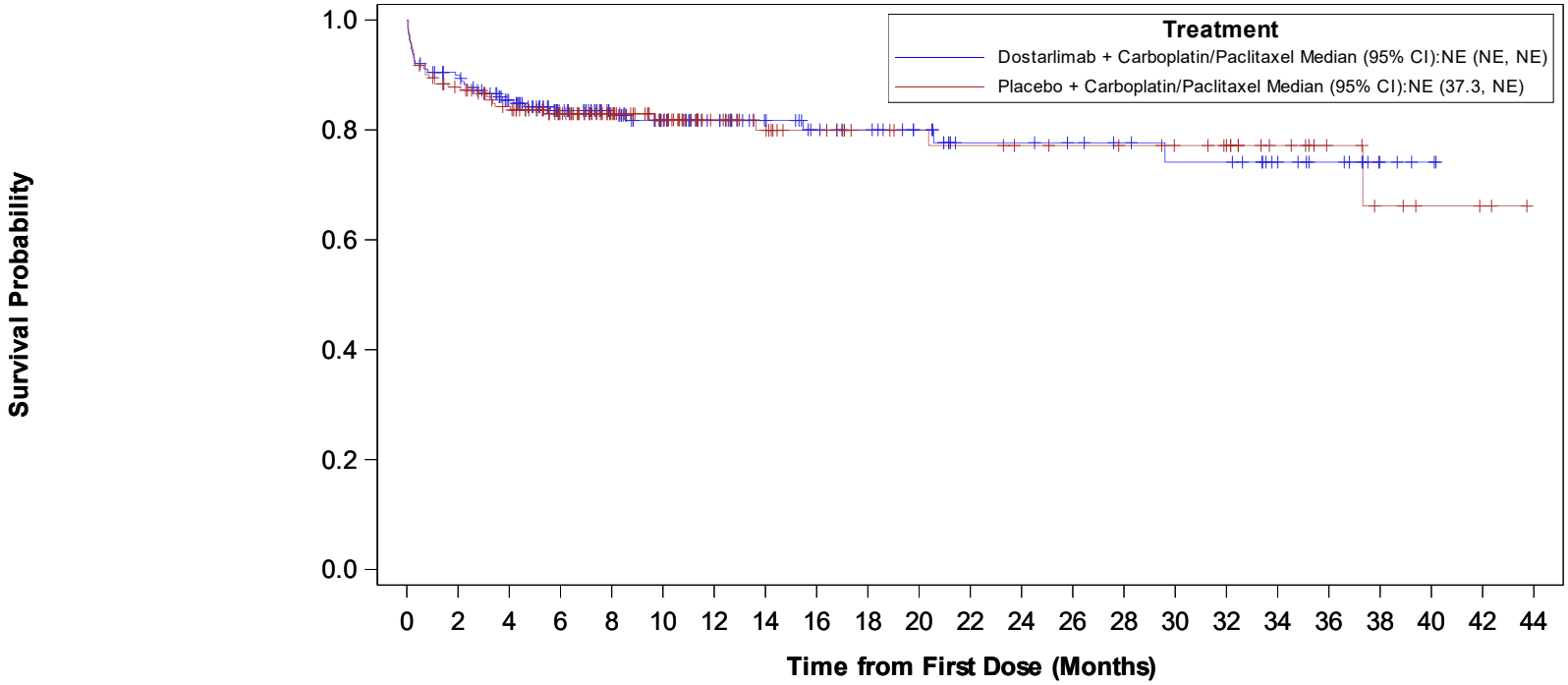
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	152(31)	122(48)	103(48)	80(51)	65(52)	53(53)	40(54)	36(54)	35(54)	29(54)	22(54)	22(54)	19(54)	18(54)	18(54)	18(54)	11(54)	8(55)	6(55)	4(55)	1(55)	0(55)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	144(31)	124(39)	103(41)	81(43)	60(46)	41(47)	35(49)	30(49)	25(50)	23(51)	23(51)	21(51)	20(51)	19(51)	17(51)	16(51)	12(51)	8(51)	6(51)	3(51)	2(51)	0(51)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Gastrointestinal disorders
Preferred Term: Vomiting



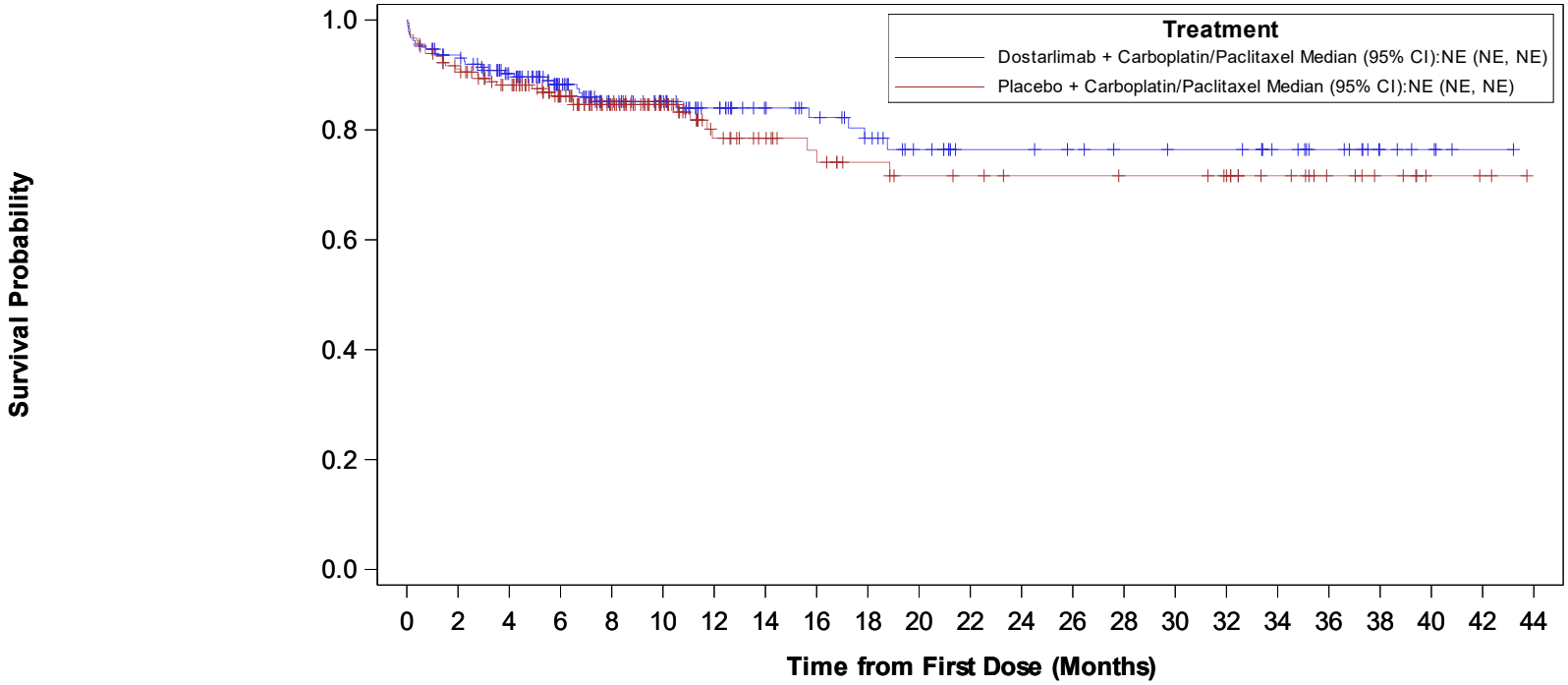
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	164(19)	142(27)	116(30)	95(31)	78(32)	66(32)	52(32)	45(33)	42(33)	36(33)	27(34)	27(34)	25(34)	23(34)	21(35)	21(35)	15(35)	11(35)	4(35)	2(35)	0(35)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	153(22)	138(28)	115(30)	89(30)	69(31)	50(31)	42(32)	36(32)	31(32)	29(32)	28(33)	26(33)	25(33)	24(33)	22(33)	20(33)	13(33)	8(33)	5(34)	3(34)	2(34)	0(34)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Gastrointestinal disorders
Preferred Term: Abdominal pain



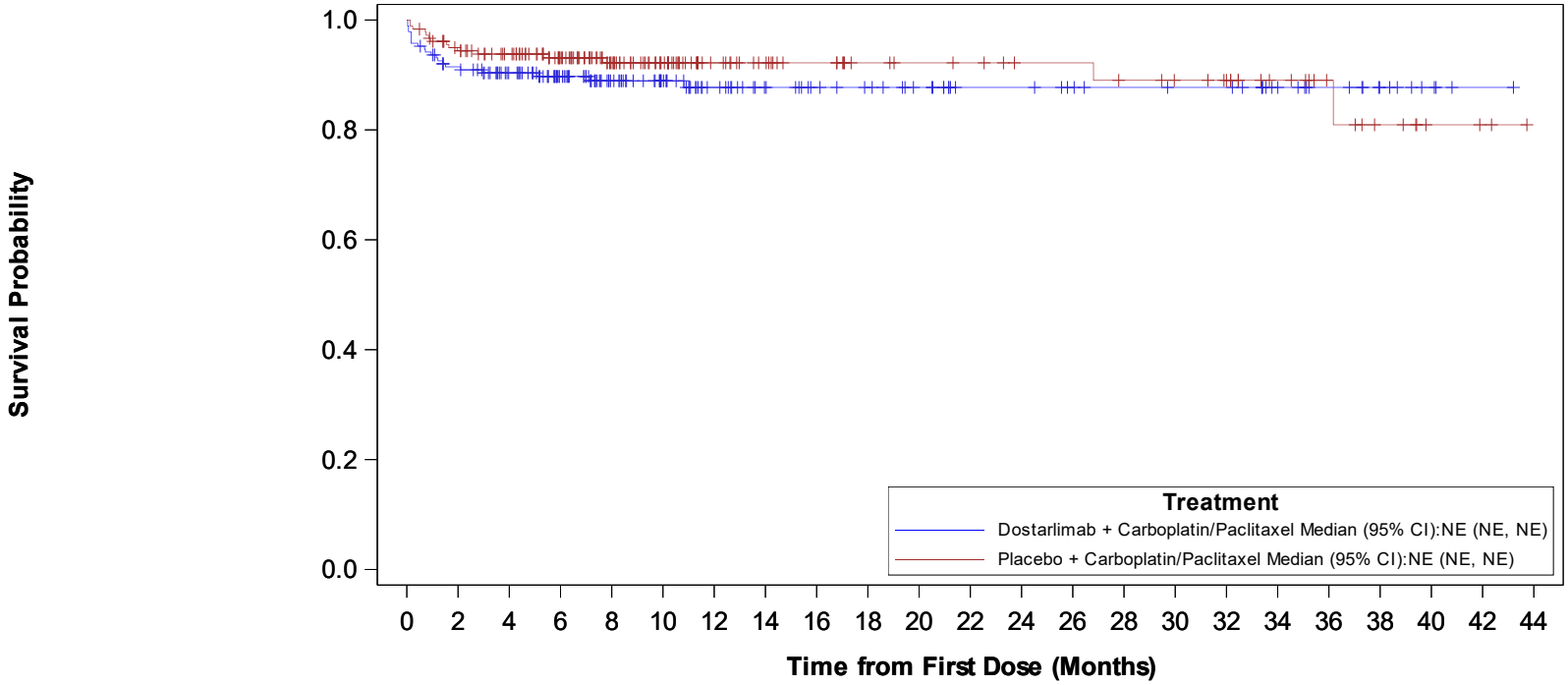
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	170(12)	148(18)	121(21)	94(25)	77(25)	63(26)	52(26)	47(27)	41(29)	34(30)	27(30)	27(30)	25(30)	23(30)	22(30)	22(30)	17(30)	13(30)	6(30)	4(30)	1(30)	0(30)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	160(16)	145(21)	118(24)	92(26)	69(26)	47(30)	40(30)	35(32)	30(32)	27(33)	26(33)	24(33)	24(33)	23(33)	23(33)	21(33)	15(33)	10(33)	7(33)	3(33)	2(33)	0(33)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Gastrointestinal disorders
Preferred Term: Dyspepsia



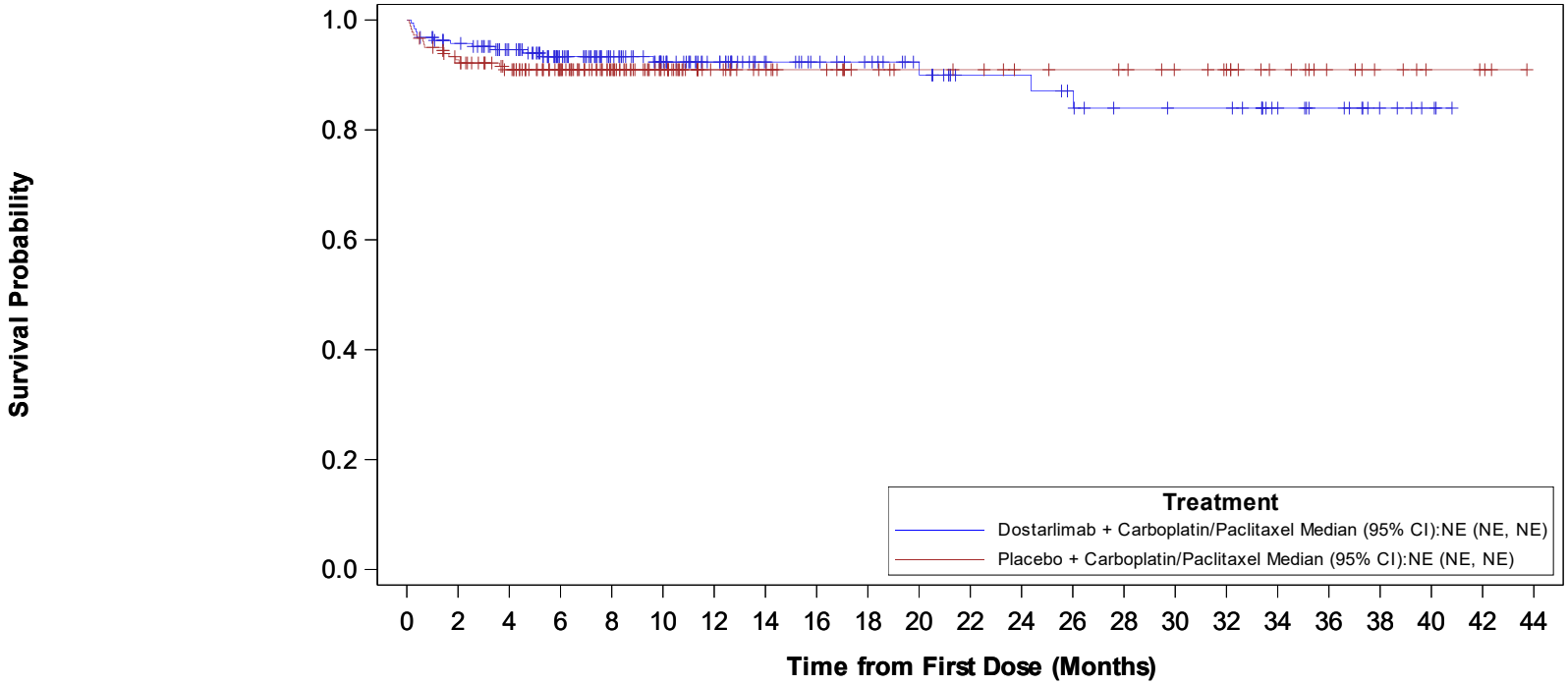
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	167(16)	149(18)	124(19)	98(20)	80(20)	63(21)	53(21)	47(21)	44(21)	39(21)	31(21)	31(21)	28(21)	26(21)	25(21)	25(21)	18(21)	13(21)	8(21)	4(21)	1(21)	0(21)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	164(10)	151(11)	126(12)	97(13)	76(13)	55(13)	47(13)	41(13)	35(13)	33(13)	32(13)	29(13)	29(13)	27(14)	25(14)	23(14)	16(14)	11(14)	7(15)	3(15)	2(15)	0(15)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Gastrointestinal disorders
Preferred Term: Stomatitis



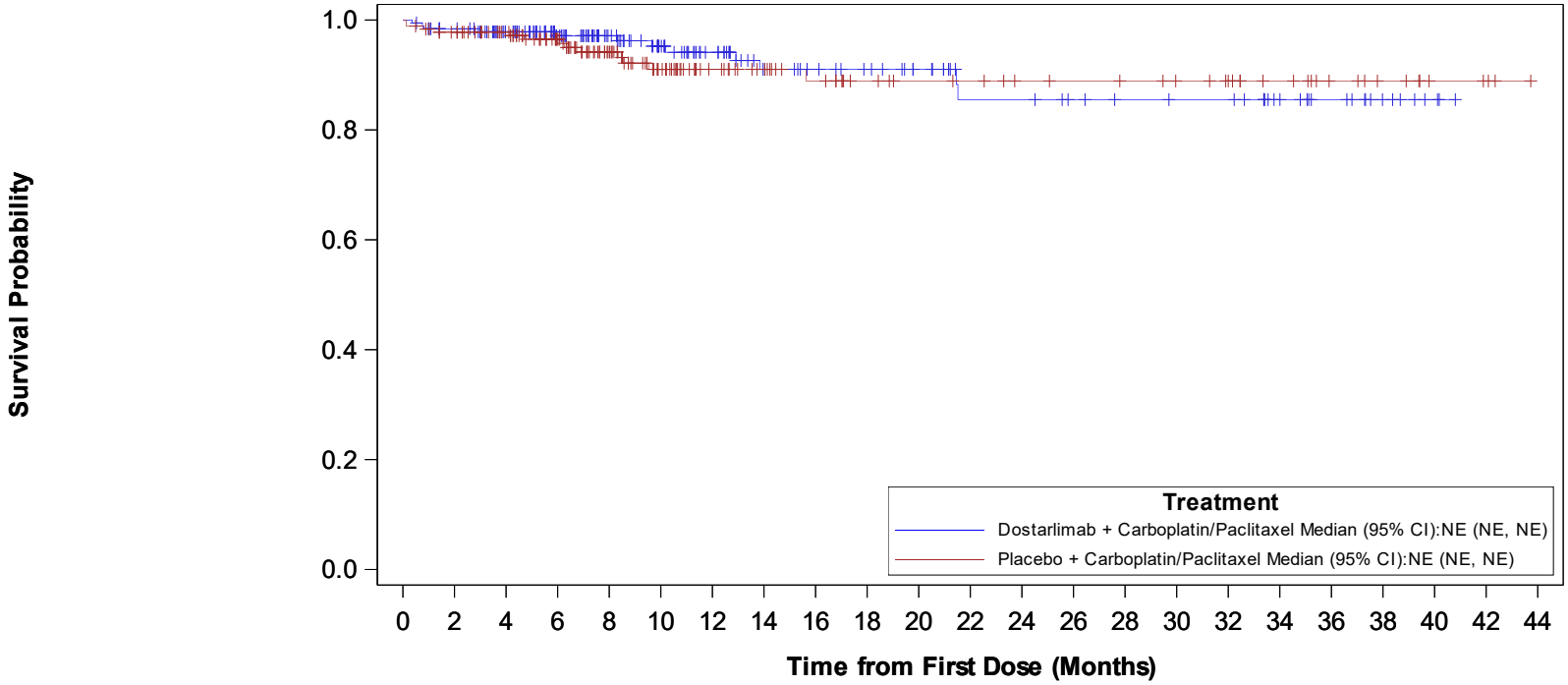
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	174(8)	157(10)	128(12)	104(12)	86(13)	70(13)	55(13)	49(13)	45(13)	39(13)	31(14)	31(14)	28(15)	24(16)	23(16)	23(16)	16(16)	12(16)	6(16)	3(16)	0(16)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	162(13)	146(16)	121(16)	95(16)	72(16)	52(16)	45(16)	41(16)	35(16)	32(16)	31(16)	28(16)	27(16)	26(16)	23(16)	21(16)	15(16)	10(16)	7(16)	4(16)	3(16)	0(16)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Gastrointestinal disorders
Preferred Term: Abdominal distension



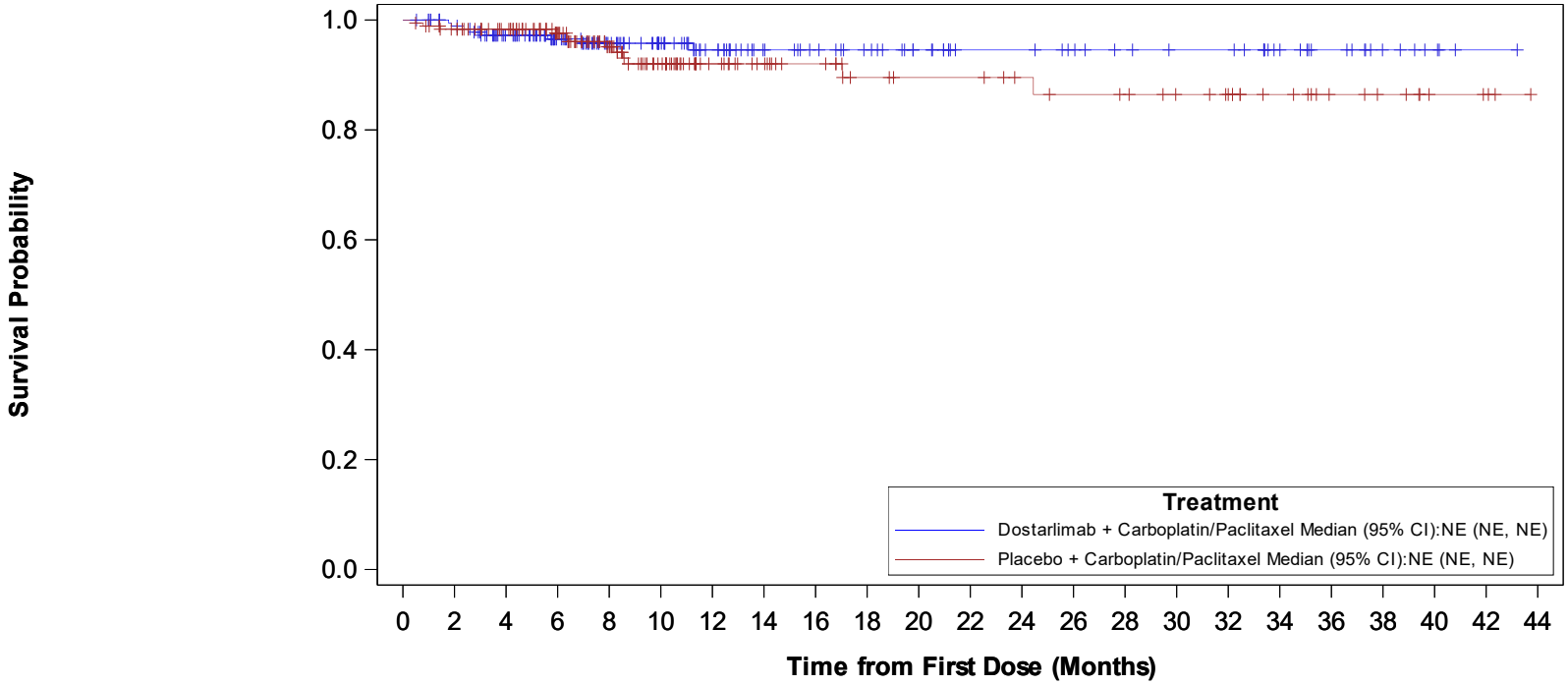
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	179(3)	161(4)	134(5)	109(5)	89(7)	72(8)	56(10)	51(10)	47(10)	41(10)	31(12)	31(12)	28(12)	26(12)	25(12)	25(12)	18(12)	13(12)	7(12)	3(12)	0(12)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	171(4)	158(4)	131(6)	100(9)	76(12)	57(12)	49(12)	42(13)	35(13)	32(13)	31(13)	28(13)	27(13)	26(13)	24(13)	22(13)	16(13)	11(13)	8(13)	4(13)	3(13)	0(13)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Gastrointestinal disorders
Preferred Term: Abdominal pain lower



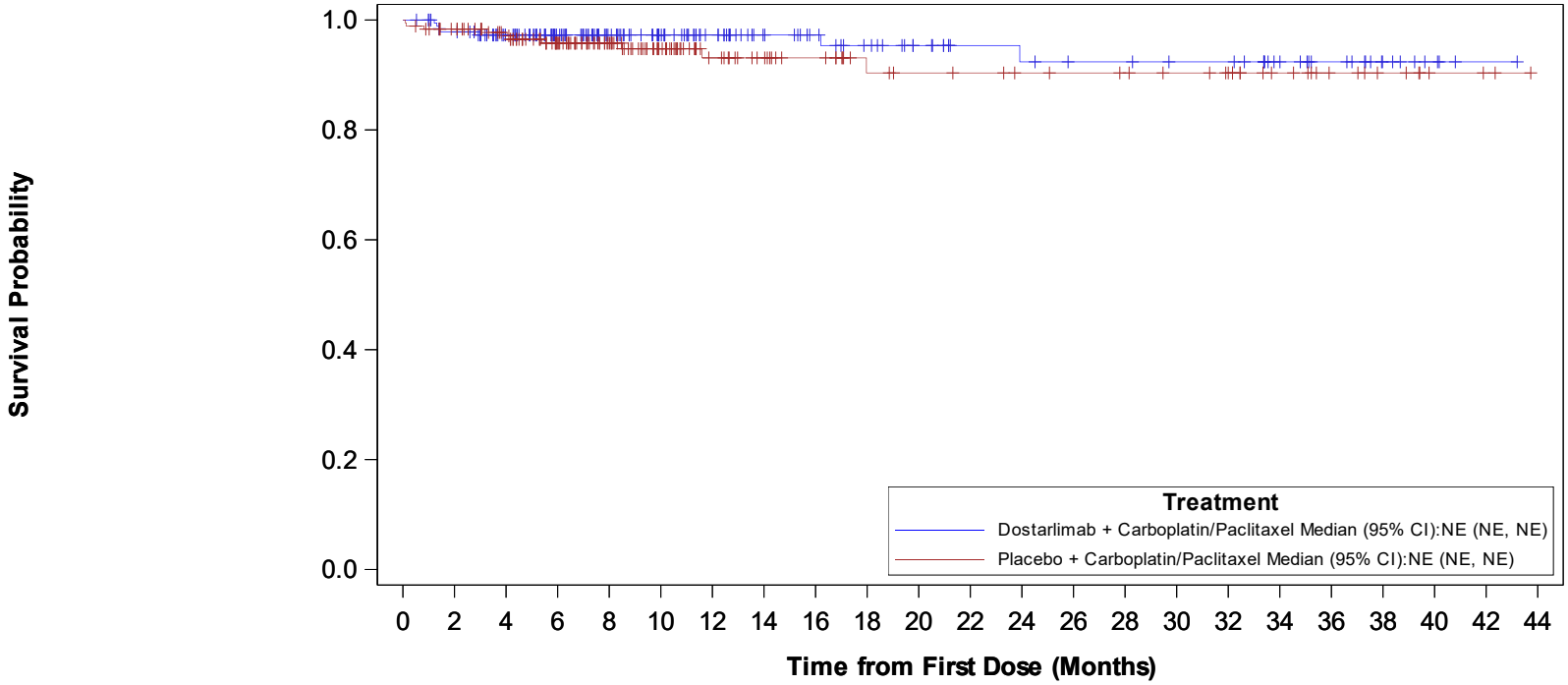
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	180(2)	160(5)	131(6)	107(7)	89(7)	72(8)	58(8)	53(8)	48(8)	41(8)	33(8)	33(8)	30(8)	27(8)	25(8)	25(8)	18(8)	13(8)	7(8)	4(8)	1(8)	0(8)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	171(3)	158(3)	131(4)	100(7)	77(10)	55(10)	47(10)	41(10)	34(11)	32(11)	32(11)	29(11)	27(12)	26(12)	23(12)	21(12)	15(12)	10(12)	8(12)	4(12)	3(12)	0(12)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Gastrointestinal disorders
Preferred Term: Abdominal pain upper



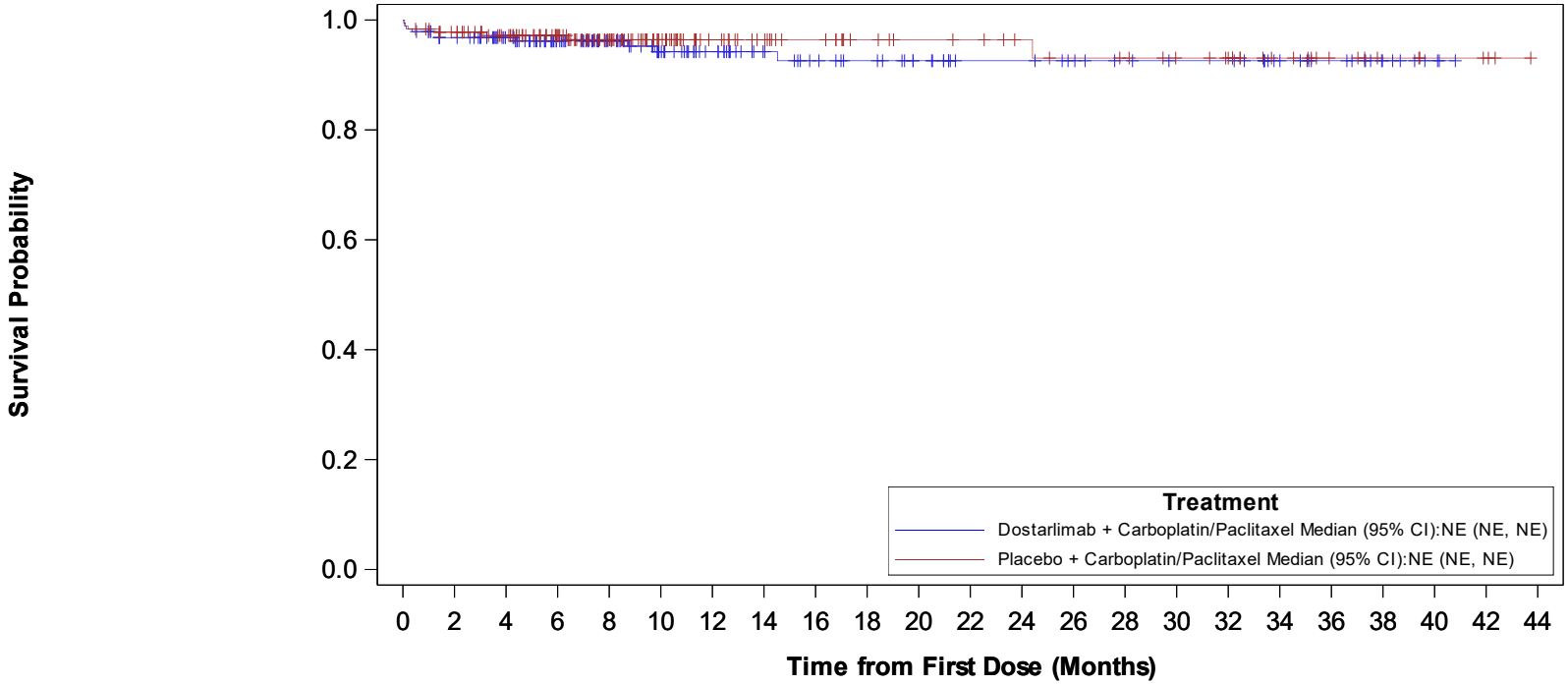
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	178(4)	161(5)	133(5)	108(5)	89(5)	73(5)	58(5)	52(5)	46(6)	39(6)	32(6)	31(7)	29(7)	29(7)	27(7)	27(7)	20(7)	15(7)	8(7)	4(7)	1(7)	0(7)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	171(3)	157(4)	129(7)	101(7)	77(8)	55(9)	47(9)	41(9)	33(10)	31(10)	30(10)	28(10)	27(10)	26(10)	24(10)	22(10)	15(10)	10(10)	7(10)	3(10)	2(10)	0(10)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Gastrointestinal disorders
Preferred Term: Gastrooesophageal reflux disease



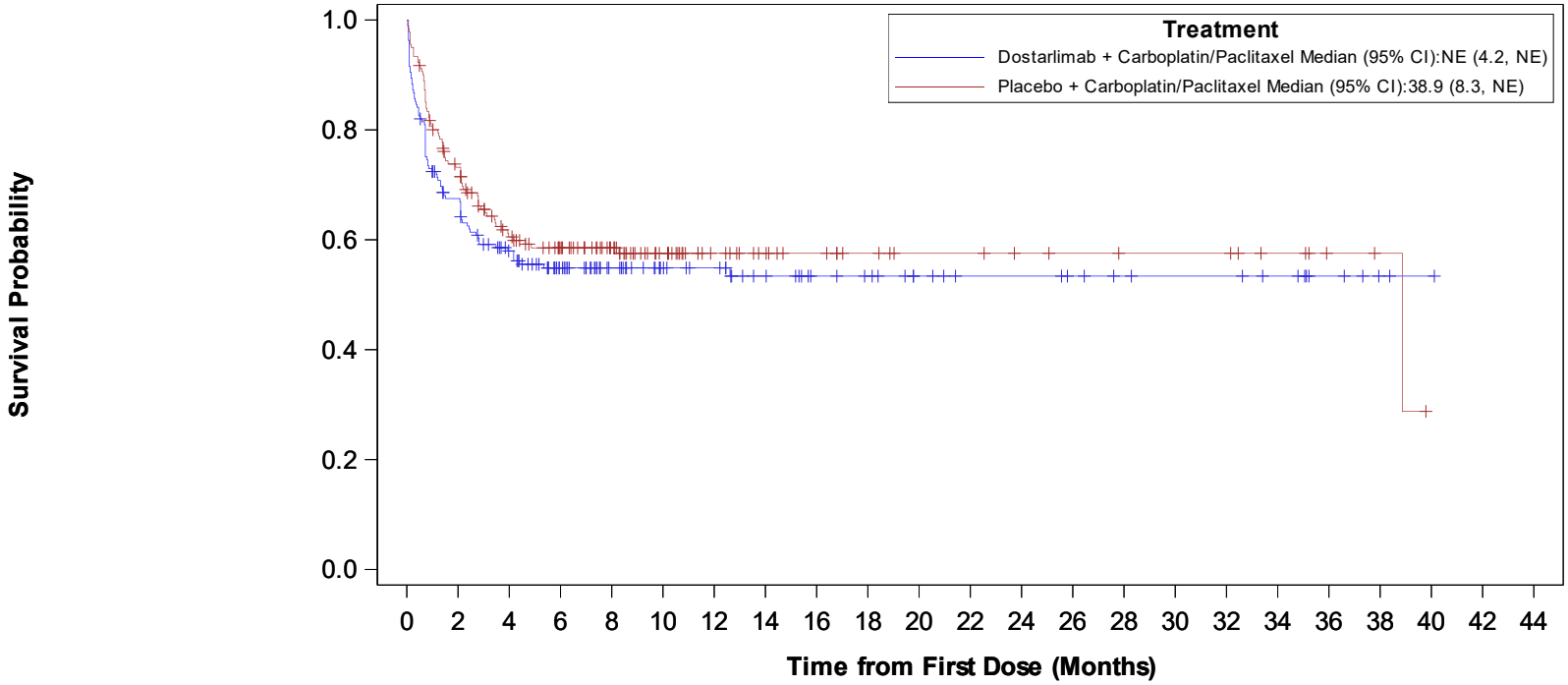
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	176(6)	160(6)	133(7)	108(7)	87(9)	72(9)	58(9)	52(10)	48(10)	42(10)	34(10)	34(10)	31(10)	28(10)	26(10)	26(10)	19(10)	14(10)	7(10)	3(10)	0(10)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	170(4)	156(5)	131(5)	102(6)	78(6)	57(6)	49(6)	43(6)	36(6)	33(6)	32(6)	29(6)	27(7)	26(7)	23(7)	21(7)	14(7)	9(7)	6(7)	4(7)	3(7)	0(7)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Neuropathy peripheral



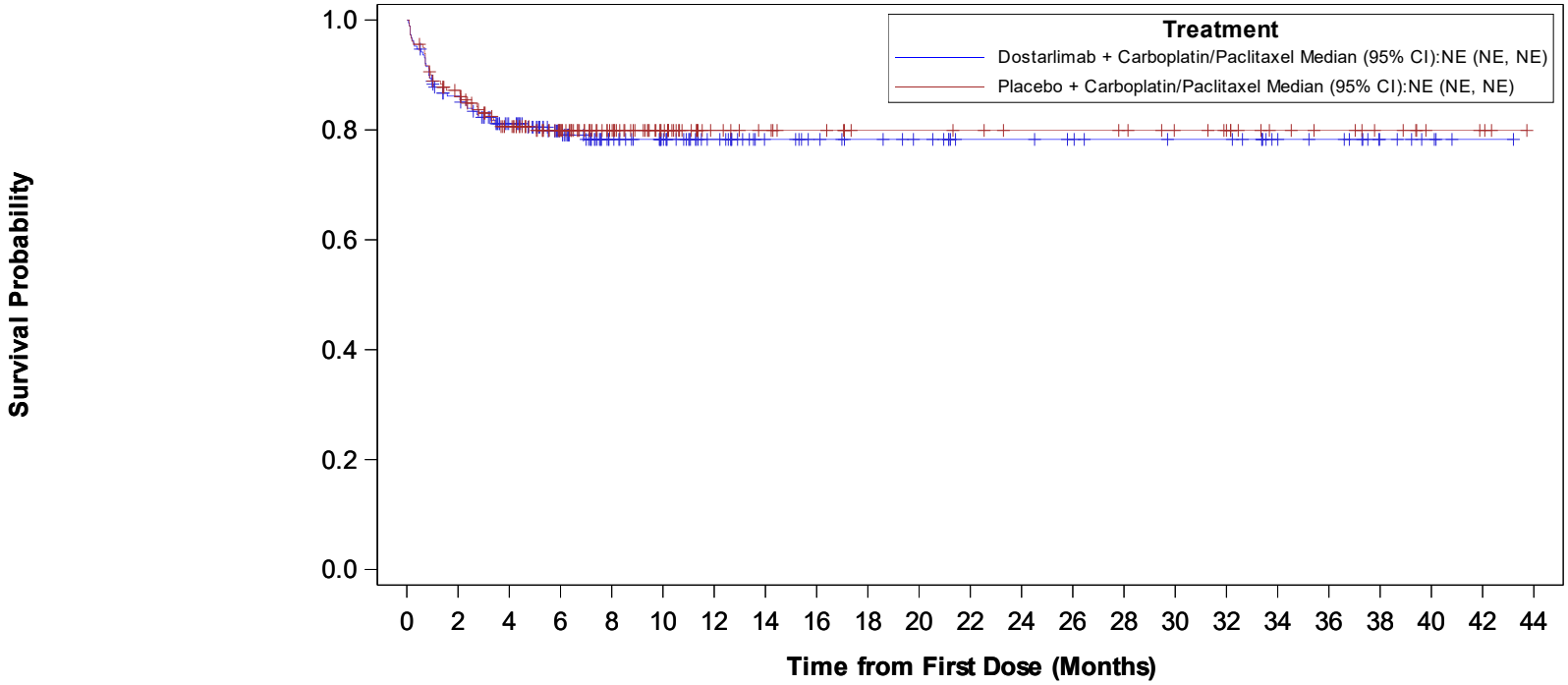
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	122(61)	96(78)	73(83)	56(83)	44(83)	40(83)	32(84)	26(84)	24(84)	19(84)	16(84)	16(84)	14(84)	12(84)	11(84)	11(84)	9(84)	5(84)	2(84)	1(84)	0(84)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	127(48)	95(69)	79(72)	62(72)	44(73)	30(73)	24(73)	20(73)	16(73)	13(73)	13(73)	11(73)	10(73)	9(73)	9(73)	9(73)	6(73)	3(73)	2(73)	0(74)	

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

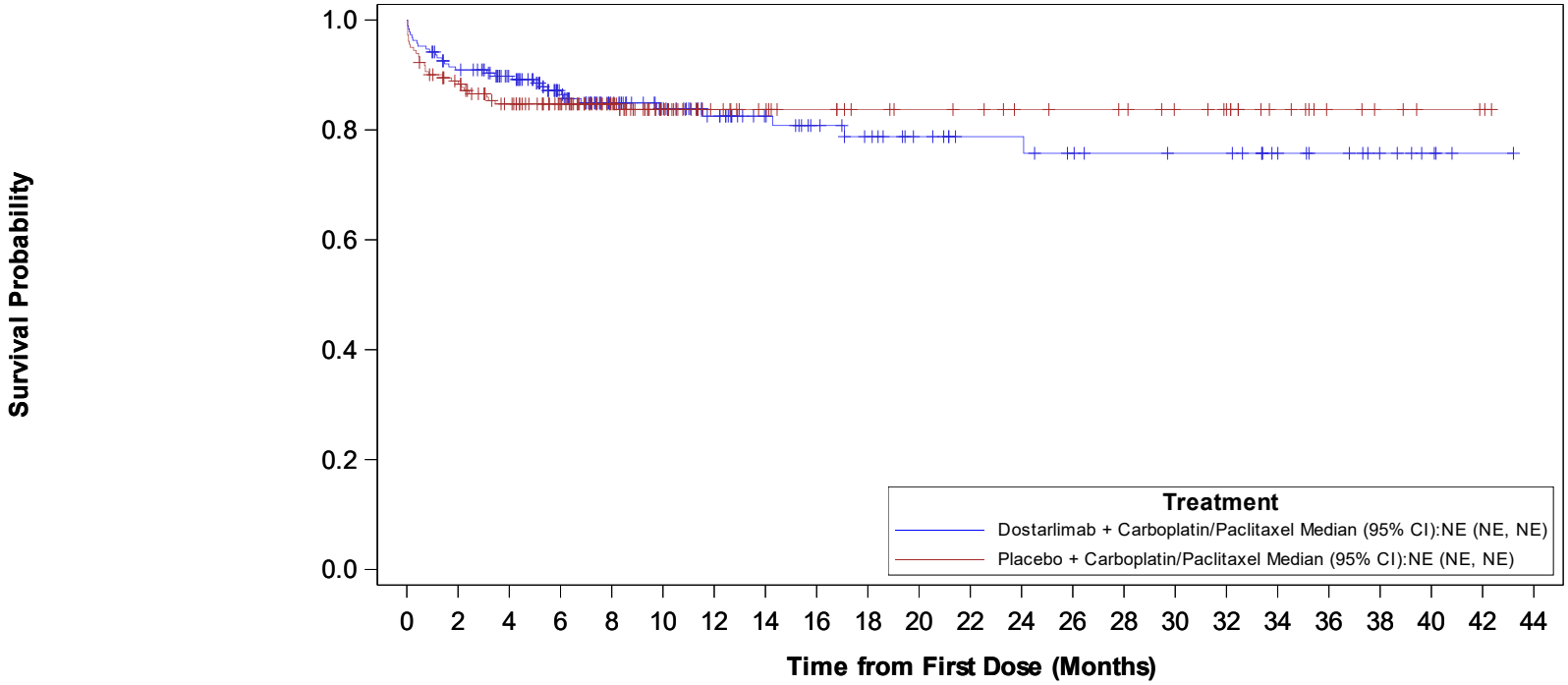
System Organ Class: Nervous system disorders
Preferred Term: Peripheral sensory neuropathy



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Headache



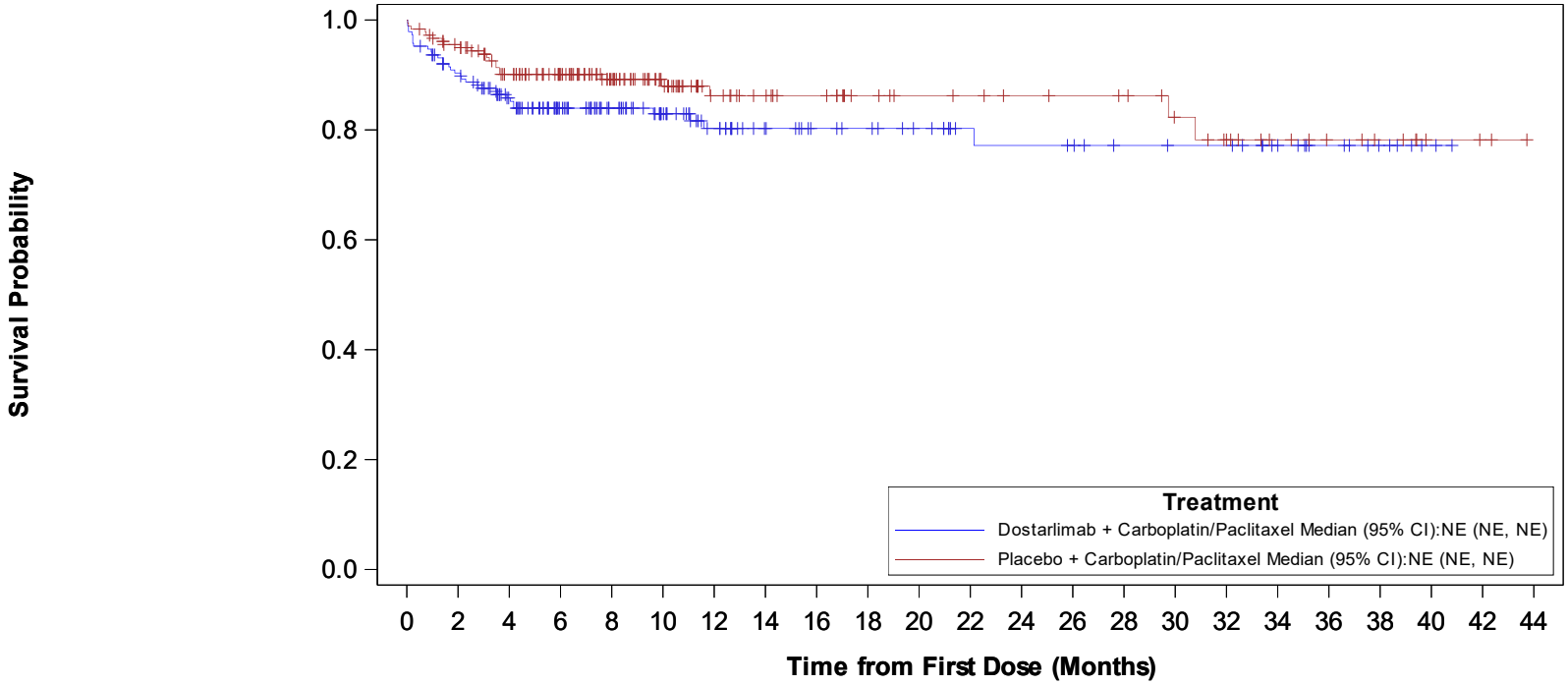
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	166(17)	147(19)	118(23)	91(26)	74(27)	61(28)	49(28)	42(29)	37(30)	31(30)	26(30)	26(30)	23(31)	21(31)	20(31)	20(31)	14(31)	11(31)	7(31)	4(31)	1(31)	0(31)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	154(20)	135(27)	116(27)	88(27)	65(28)	46(28)	40(28)	36(28)	32(28)	30(28)	29(28)	26(28)	25(28)	24(28)	21(28)	19(28)	12(28)	7(28)	5(28)	3(28)	2(28)	0(28)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Dizziness



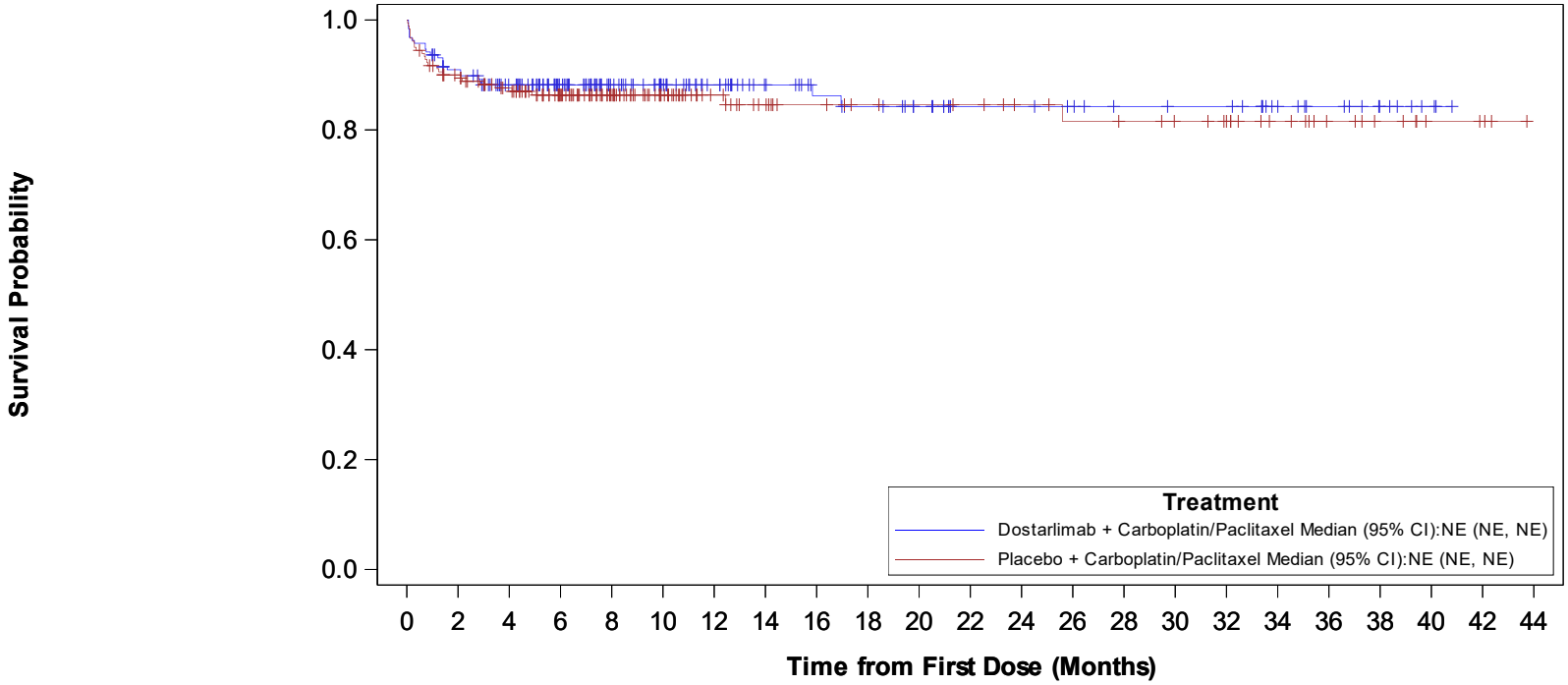
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	164(18)	139(26)	111(29)	91(29)	73(30)	57(32)	45(32)	39(32)	37(32)	33(32)	26(32)	25(33)	24(33)	21(33)	20(33)	20(33)	15(33)	10(33)	6(33)	2(33)	0(33)	
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	166(8)	144(17)	121(17)	94(18)	70(19)	49(20)	43(20)	39(20)	32(20)	29(20)	28(20)	26(20)	25(20)	24(20)	20(21)	17(22)	12(22)	9(22)	7(22)	3(22)	2(22)	0(22)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Dysgeusia



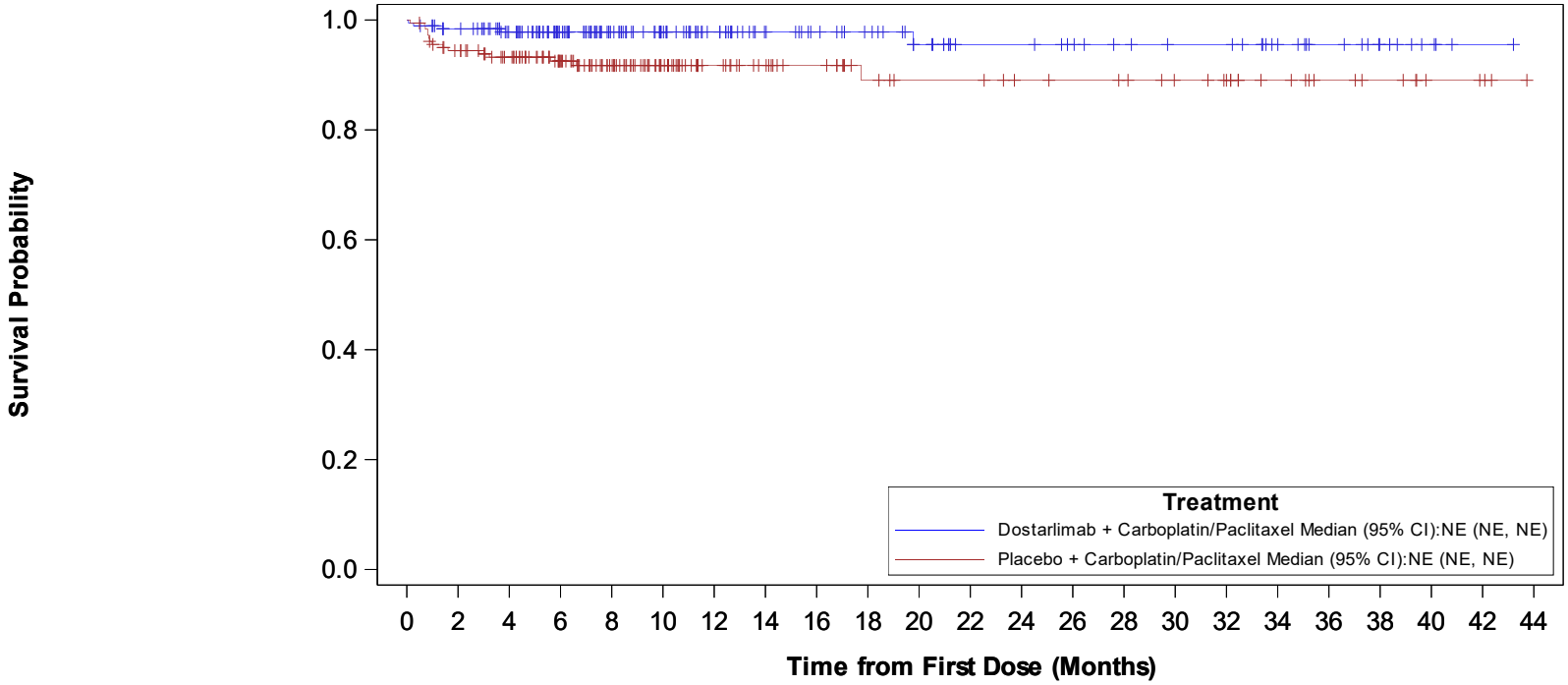
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	166(17)	147(22)	121(22)	95(22)	78(22)	64(22)	51(22)	44(23)	41(24)	36(24)	29(24)	29(24)	27(24)	24(24)	23(24)	23(24)	16(24)	12(24)	7(24)	3(24)	0(24)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	156(18)	141(22)	115(24)	89(24)	67(24)	50(24)	42(25)	37(25)	34(25)	33(25)	32(25)	29(25)	27(26)	26(26)	24(26)	22(26)	16(26)	11(26)	8(26)	4(26)	3(26)	0(26)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia



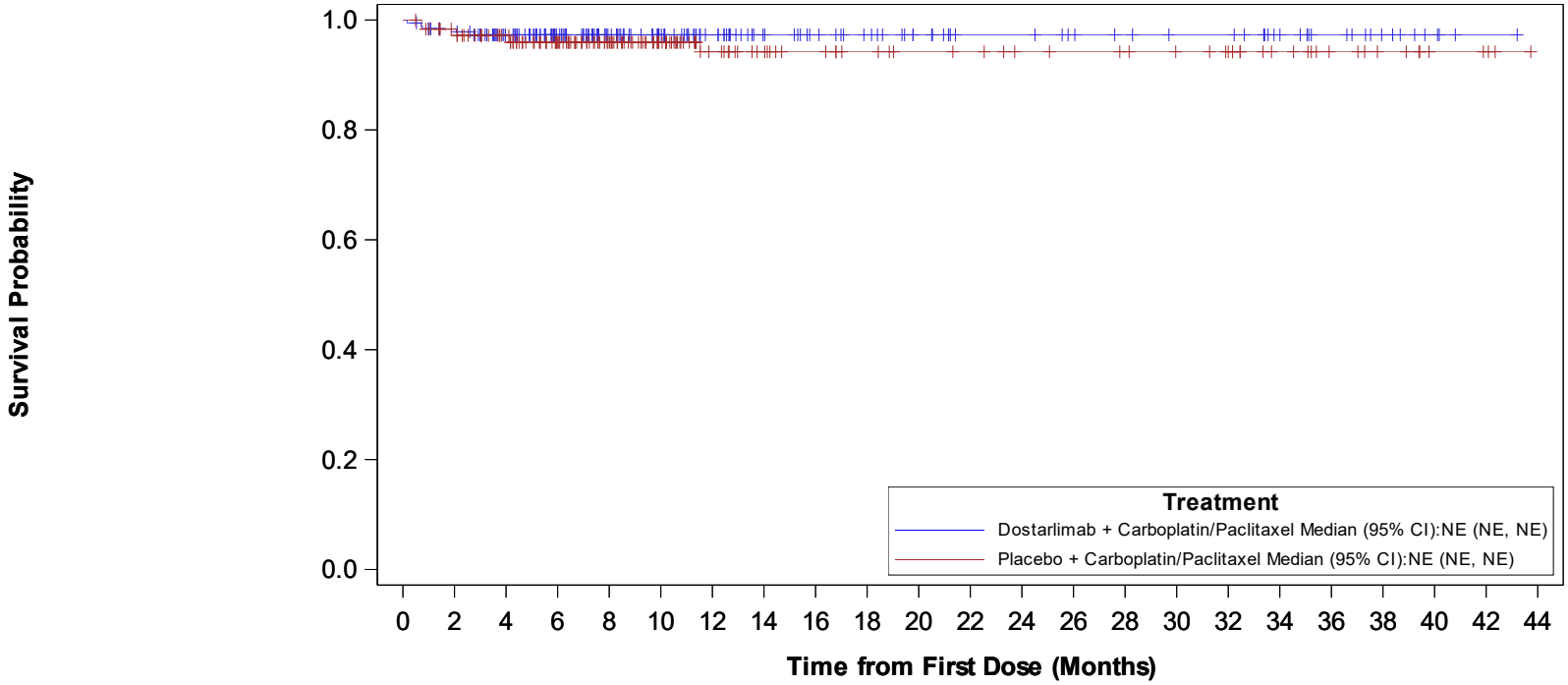
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	179(3)	162(4)	134(4)	108(4)	90(4)	74(4)	59(4)	53(4)	48(4)	40(5)	32(5)	32(5)	29(5)	26(5)	24(5)	24(5)	18(5)	13(5)	8(5)	4(5)	1(5)	0(5)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	165(10)	151(12)	124(13)	100(14)	75(14)	55(14)	47(14)	41(14)	33(15)	30(15)	30(15)	27(15)	26(15)	25(15)	22(15)	20(15)	14(15)	10(15)	8(15)	4(15)	3(15)	0(15)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Taste disorder



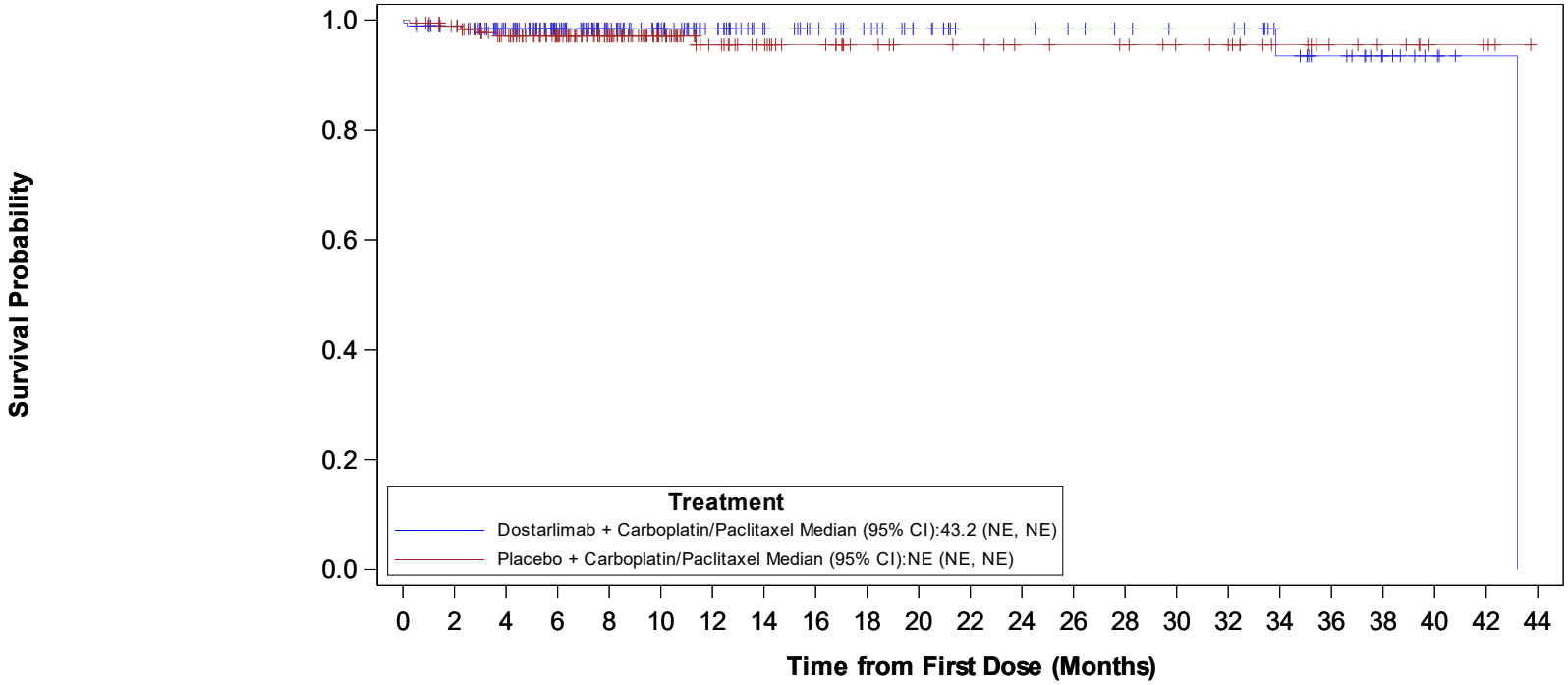
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	179(3)	160(5)	132(5)	107(5)	88(5)	72(5)	57(5)	51(5)	46(5)	39(5)	32(5)	32(5)	29(5)	27(5)	25(5)	25(5)	18(5)	13(5)	8(5)	4(5)	1(5)	0(5)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	171(3)	156(5)	128(7)	100(7)	76(7)	53(8)	45(8)	40(8)	36(8)	33(8)	32(8)	29(8)	28(8)	27(8)	25(8)	23(8)	16(8)	11(8)	8(8)	4(8)	3(8)	0(8)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Syncope



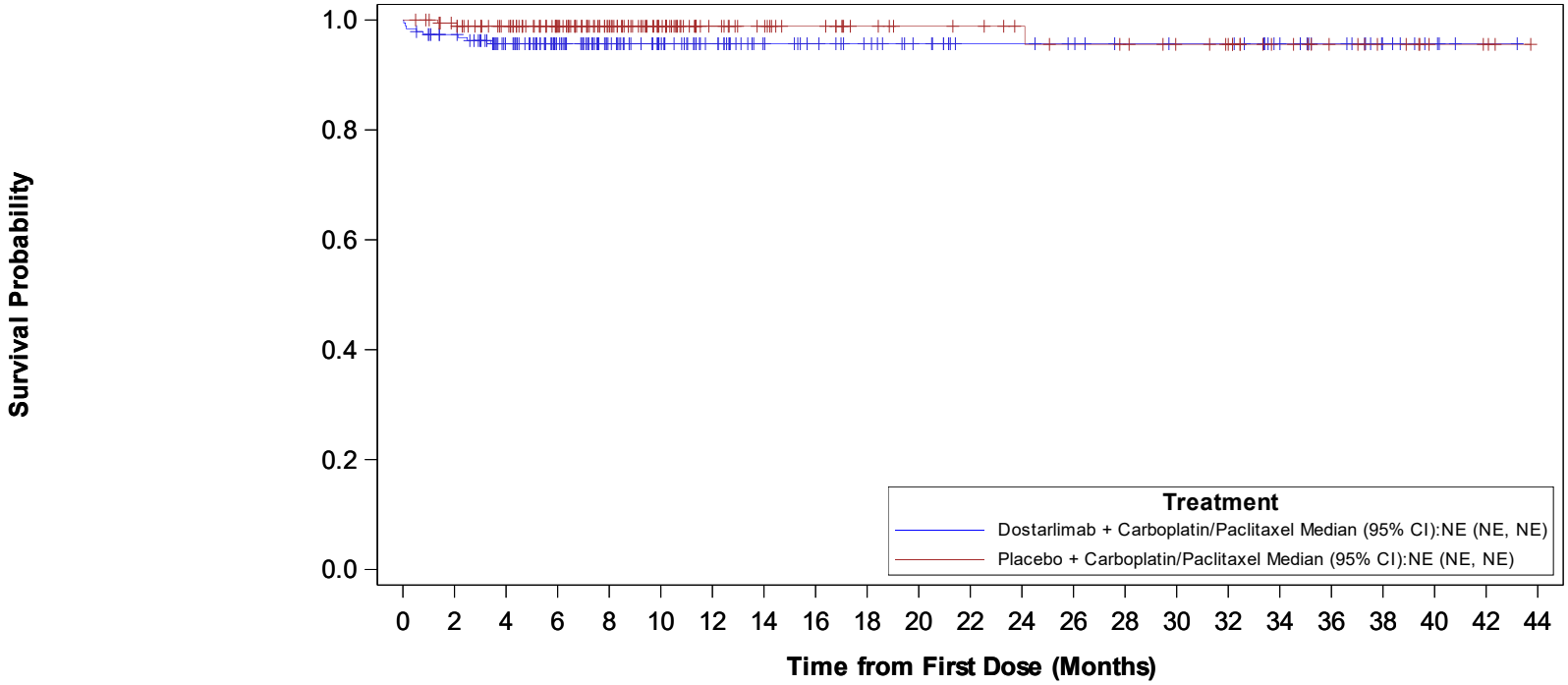
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	180(2)	163(3)	135(3)	109(3)	90(3)	74(3)	59(3)	53(3)	48(3)	41(3)	33(3)	33(3)	31(3)	29(3)	27(3)	27(3)	19(4)	15(4)	8(4)	4(4)	1(4)	0(5)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	172(2)	156(5)	130(5)	103(5)	77(5)	55(6)	47(6)	41(6)	34(6)	31(6)	30(6)	27(6)	26(6)	25(6)	22(6)	21(6)	14(6)	10(6)	8(6)	4(6)	3(6)	0(6)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Tremor



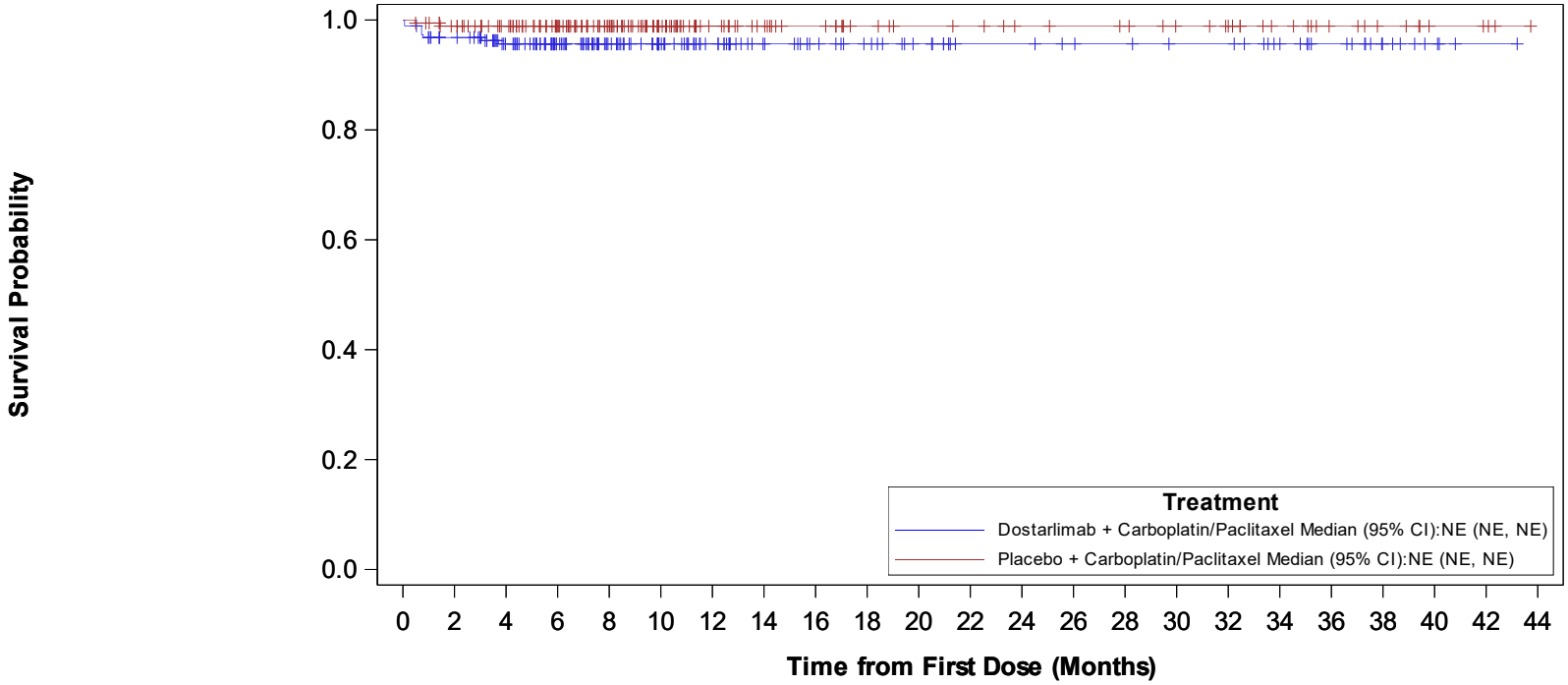
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	178(5)	158(8)	131(8)	106(8)	87(8)	72(8)	57(8)	52(8)	47(8)	41(8)	33(8)	33(8)	31(8)	28(8)	27(8)	27(8)	20(8)	15(8)	8(8)	4(8)	1(8)	0(8)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	173(1)	159(2)	133(2)	104(2)	79(2)	57(2)	50(2)	44(2)	37(2)	34(2)	33(2)	30(2)	28(3)	27(3)	24(3)	22(3)	15(3)	11(3)	8(3)	4(3)	3(3)	0(3)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Hypoaesthesia



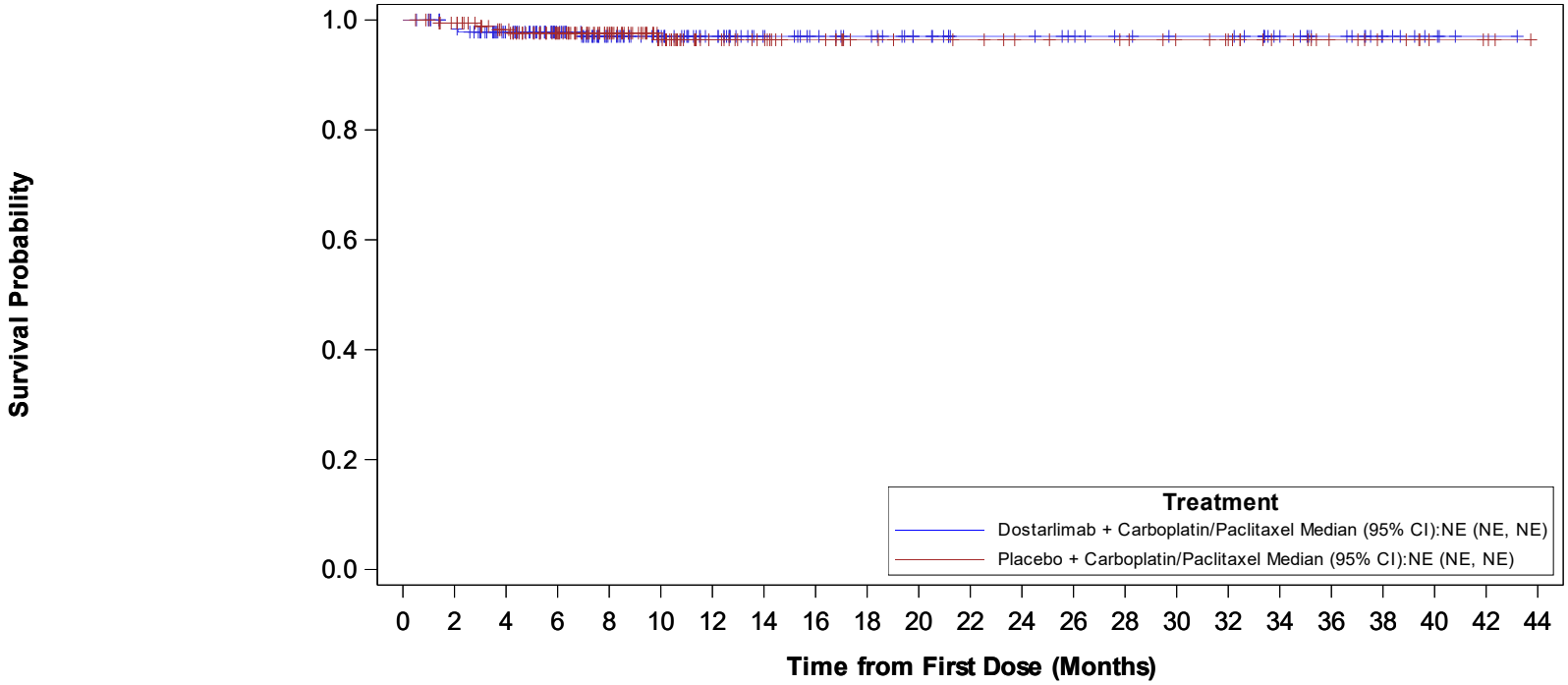
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	176(6)	157(8)	130(8)	104(8)	85(8)	69(8)	55(8)	49(8)	44(8)	38(8)	30(8)	30(8)	28(8)	27(8)	25(8)	25(8)	20(8)	15(8)	8(8)	4(8)	1(8)	0(8)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	172(2)	159(2)	133(2)	106(2)	80(2)	58(2)	50(2)	44(2)	37(2)	34(2)	33(2)	30(2)	29(2)	28(2)	25(2)	23(2)	16(2)	11(2)	8(2)	4(2)	3(2)	0(2)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Memory impairment



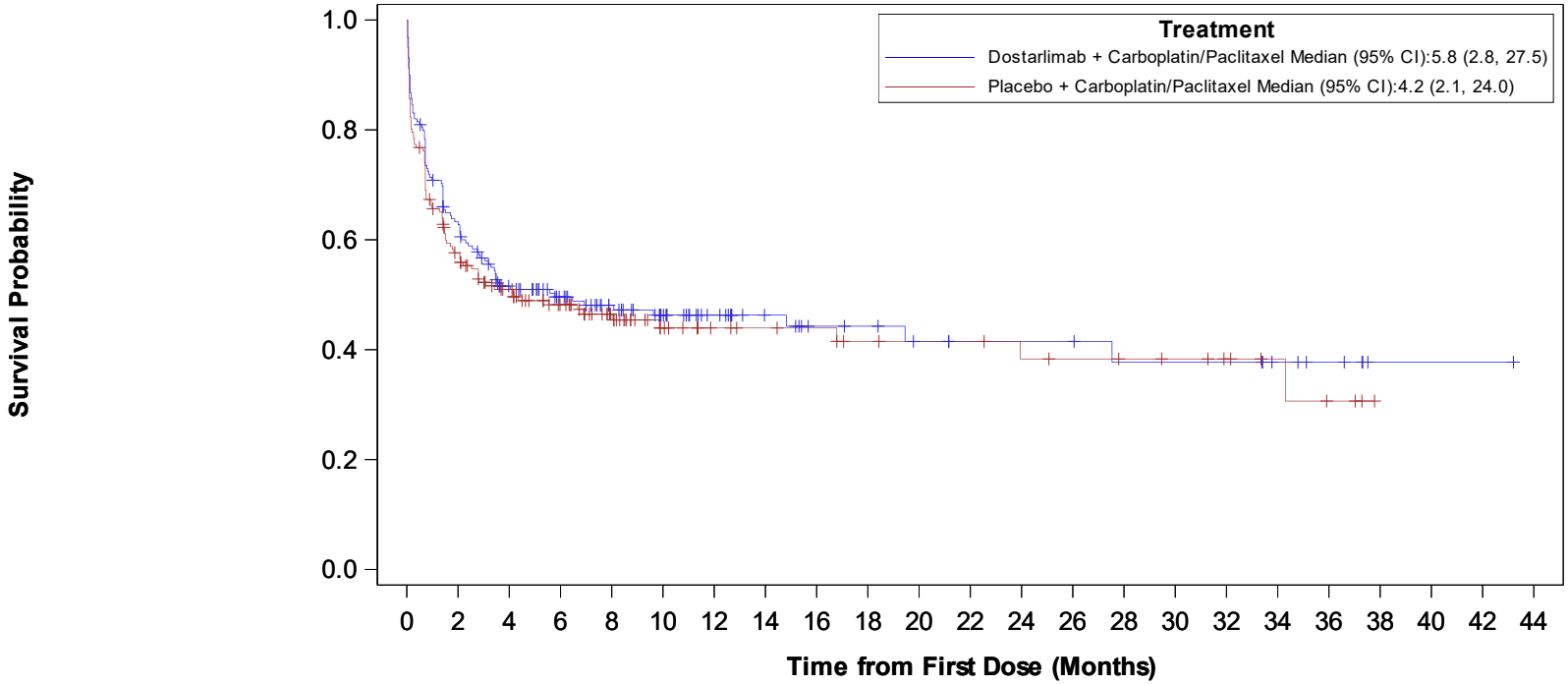
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	181(1)	161(4)	133(4)	107(5)	88(5)	73(5)	58(5)	52(5)	48(5)	41(5)	35(5)	35(5)	32(5)	29(5)	27(5)	27(5)	20(5)	15(5)	8(5)	4(5)	1(5)	0(5)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	173(1)	158(3)	133(4)	104(4)	77(5)	56(5)	49(5)	43(5)	36(5)	34(5)	33(5)	30(5)	29(5)	28(5)	25(5)	23(5)	16(5)	11(5)	8(5)	4(5)	3(5)	0(5)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: General disorders and administration site conditions
Preferred Term: Fatigue

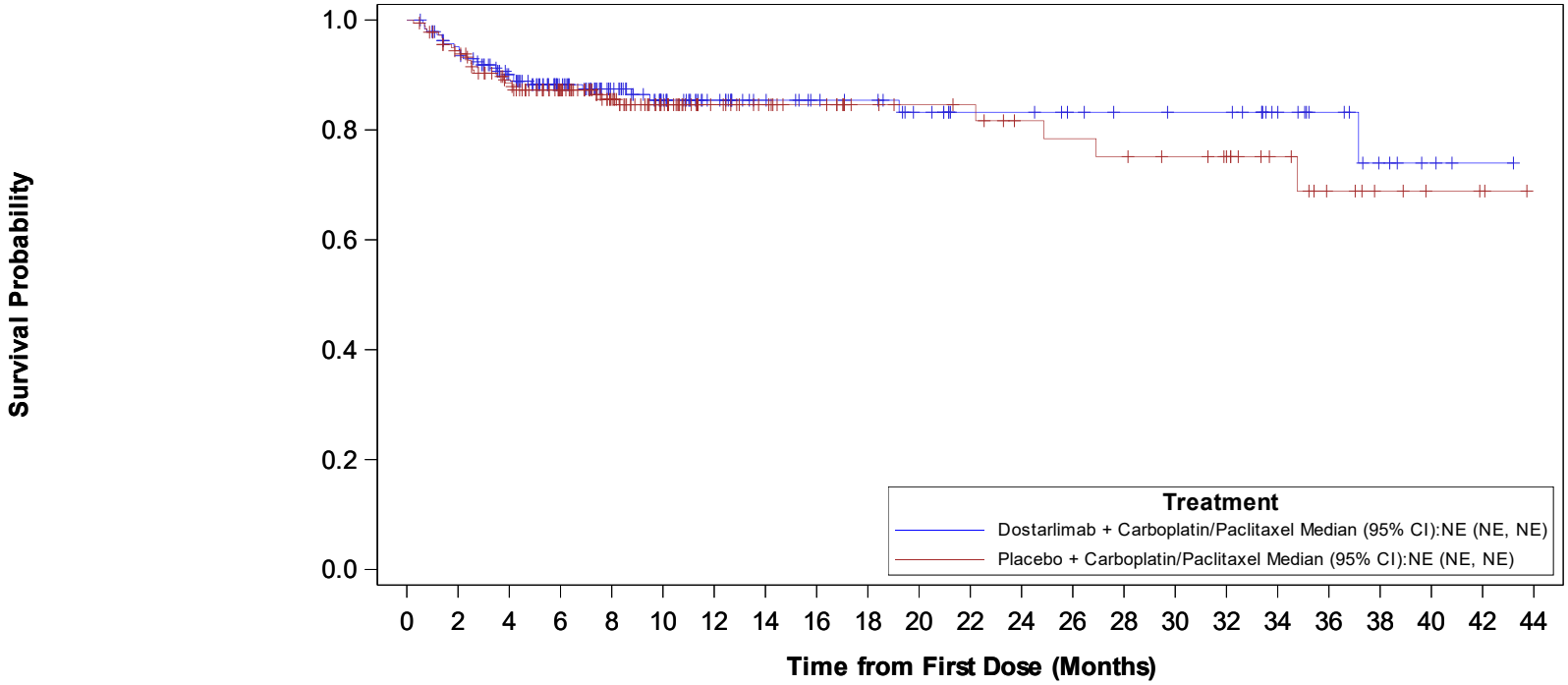


Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	116(69)	85(90)	69(93)	56(95)	44(97)	32(97)	23(97)	18(98)	17(98)	14(99)	12(99)	12(99)	12(99)	10(100)	10(100)	10(100)	7(100)	5(100)	1(100)	1(100)	1(100)	0(100)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	99(76)	77(87)	61(91)	44(93)	28(95)	21(95)	19(95)	18(95)	15(96)	14(96)	14(96)	12(97)	11(97)	10(97)	9(97)	7(97)	5(97)	3(98)	0(98)			

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: General disorders and administration site conditions
Preferred Term: Oedema peripheral



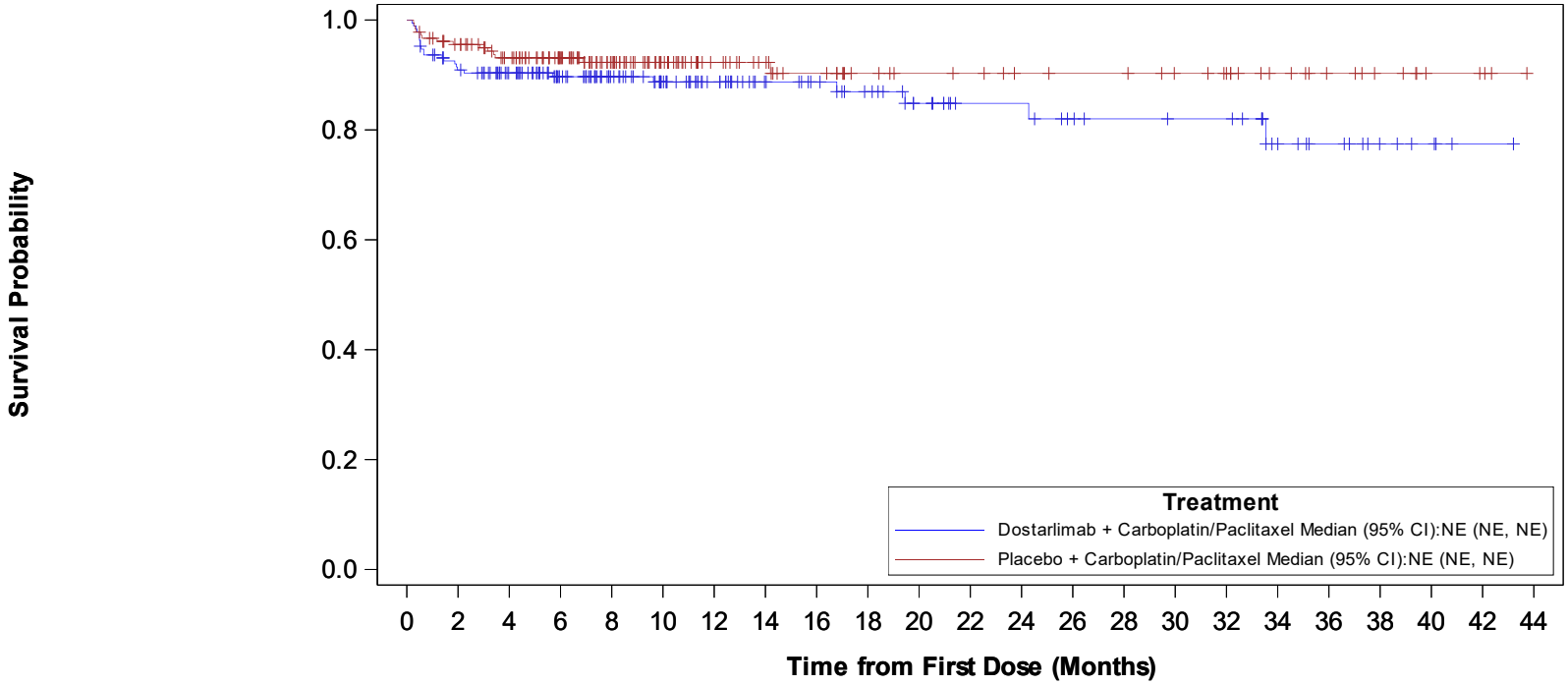
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	173(9)	149(18)	119(21)	94(22)	74(24)	59(24)	48(24)	43(24)	41(24)	35(25)	29(25)	29(25)	26(25)	24(25)	23(25)	23(25)	16(25)	11(25)	6(26)	3(26)	1(26)	0(26)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	165(10)	144(20)	120(22)	93(24)	70(25)	51(25)	44(25)	39(25)	32(25)	30(25)	29(25)	25(26)	24(27)	23(28)	21(28)	19(28)	13(28)	8(29)	5(29)	3(29)	2(29)	0(29)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: General disorders and administration site conditions
Preferred Term: Pyrexia

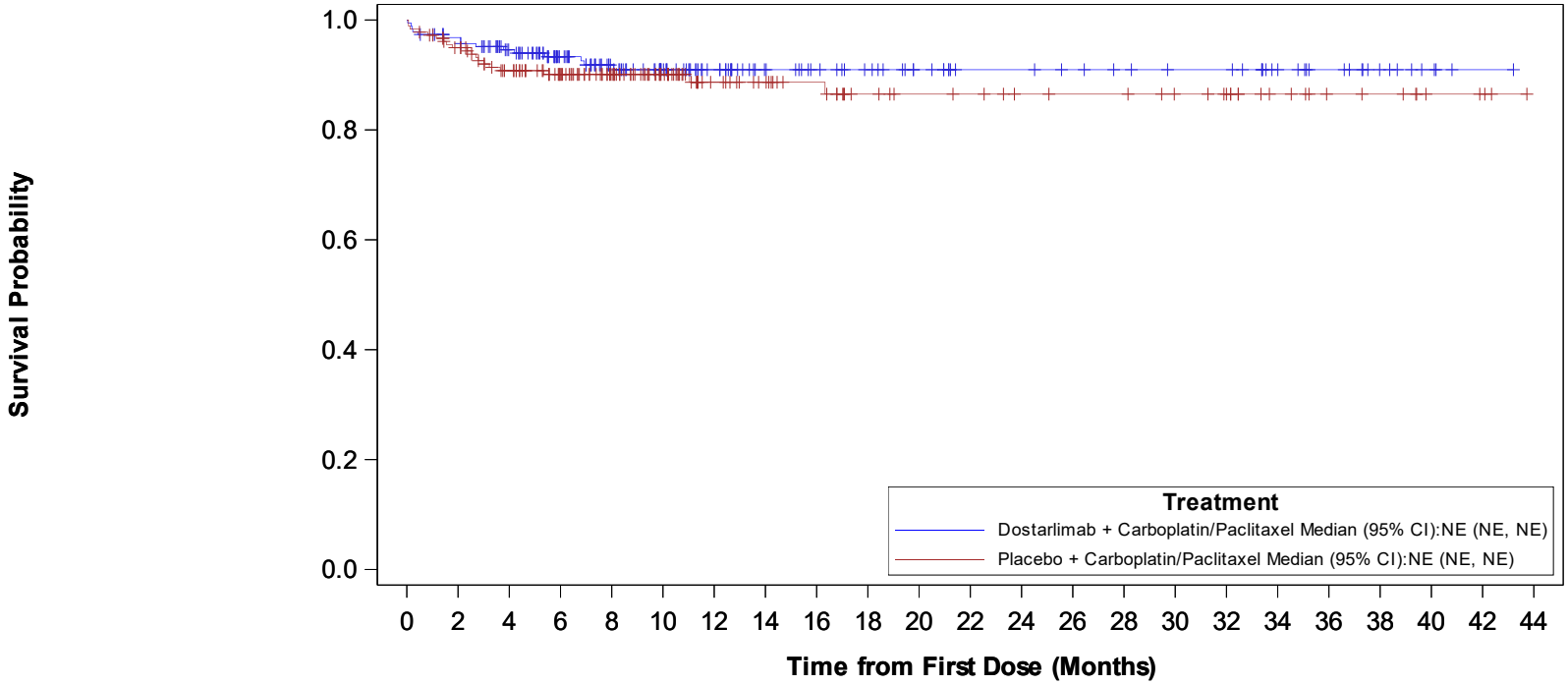


Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	166(17)	149(18)	124(19)	103(19)	85(20)	70(20)	56(20)	51(20)	45(21)	37(22)	30(22)	30(22)	26(23)	24(23)	23(23)	23(23)	15(24)	11(24)	6(24)	4(24)	1(24)	0(24)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	166(8)	149(12)	125(12)	99(13)	75(13)	55(13)	48(13)	41(14)	34(14)	31(14)	30(14)	27(14)	26(14)	26(14)	23(14)	21(14)	15(14)	11(14)	8(14)	4(14)	3(14)	0(14)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: General disorders and administration site conditions
Preferred Term: Asthenia



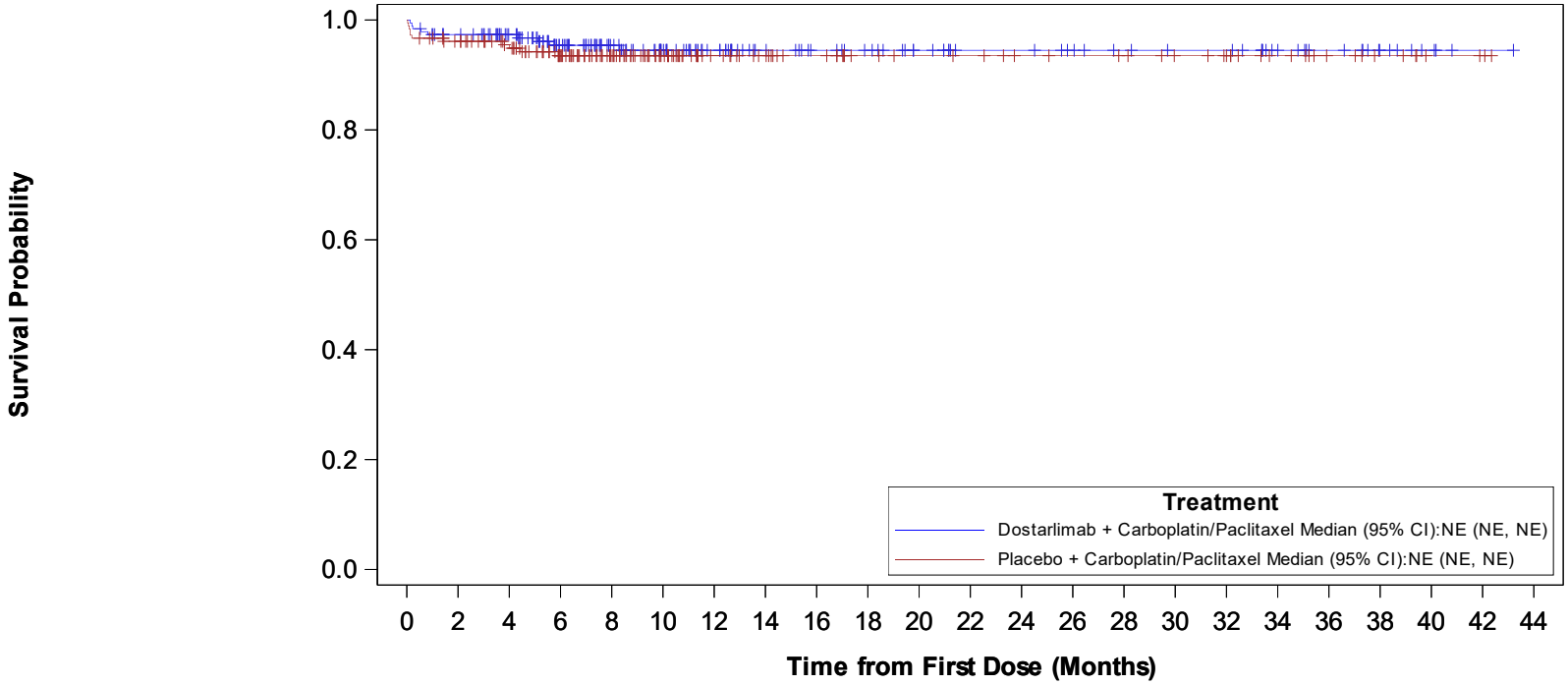
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	177(6)	158(10)	129(12)	107(14)	88(15)	72(15)	57(15)	51(15)	46(15)	39(15)	32(15)	32(15)	30(15)	28(15)	26(15)	26(15)	19(15)	14(15)	8(15)	4(15)	1(15)	0(15)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	165(9)	146(16)	124(17)	101(17)	77(17)	54(18)	47(18)	41(18)	33(19)	30(19)	29(19)	26(19)	25(19)	25(19)	22(19)	20(19)	13(19)	9(19)	8(19)	4(19)	3(19)	0(19)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: General disorders and administration site conditions
Preferred Term: Pain

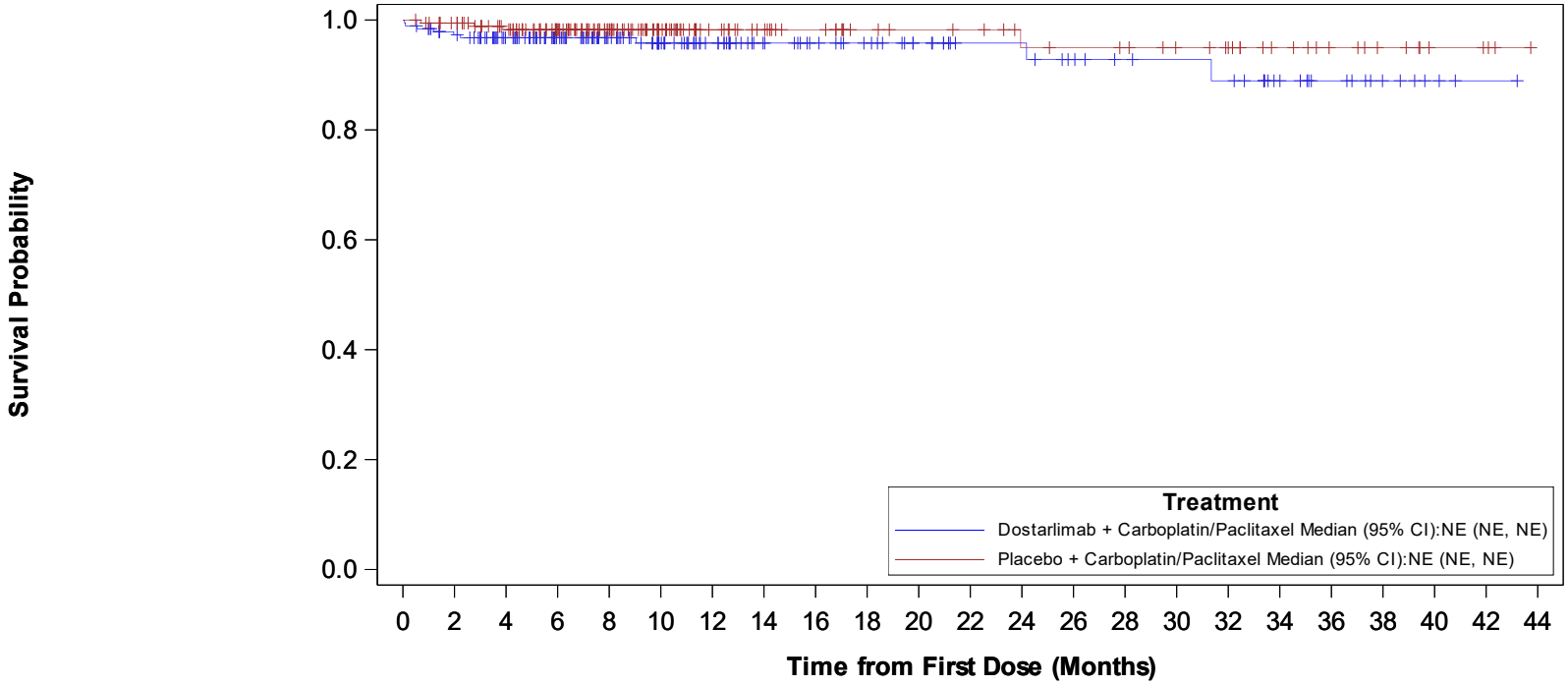


Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	177(5)	161(5)	132(8)	107(8)	88(9)	72(9)	58(9)	52(9)	48(9)	41(9)	34(9)	34(9)	31(9)	28(9)	26(9)	26(9)	19(9)	14(9)	8(9)	4(9)	1(9)	0(9)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	167(7)	153(8)	126(11)	99(11)	75(11)	54(11)	47(11)	41(11)	34(11)	32(11)	31(11)	28(11)	27(11)	26(11)	23(11)	21(11)	15(11)	10(11)	7(11)	3(11)	2(11)	0(11)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: General disorders and administration site conditions
Preferred Term: Chills

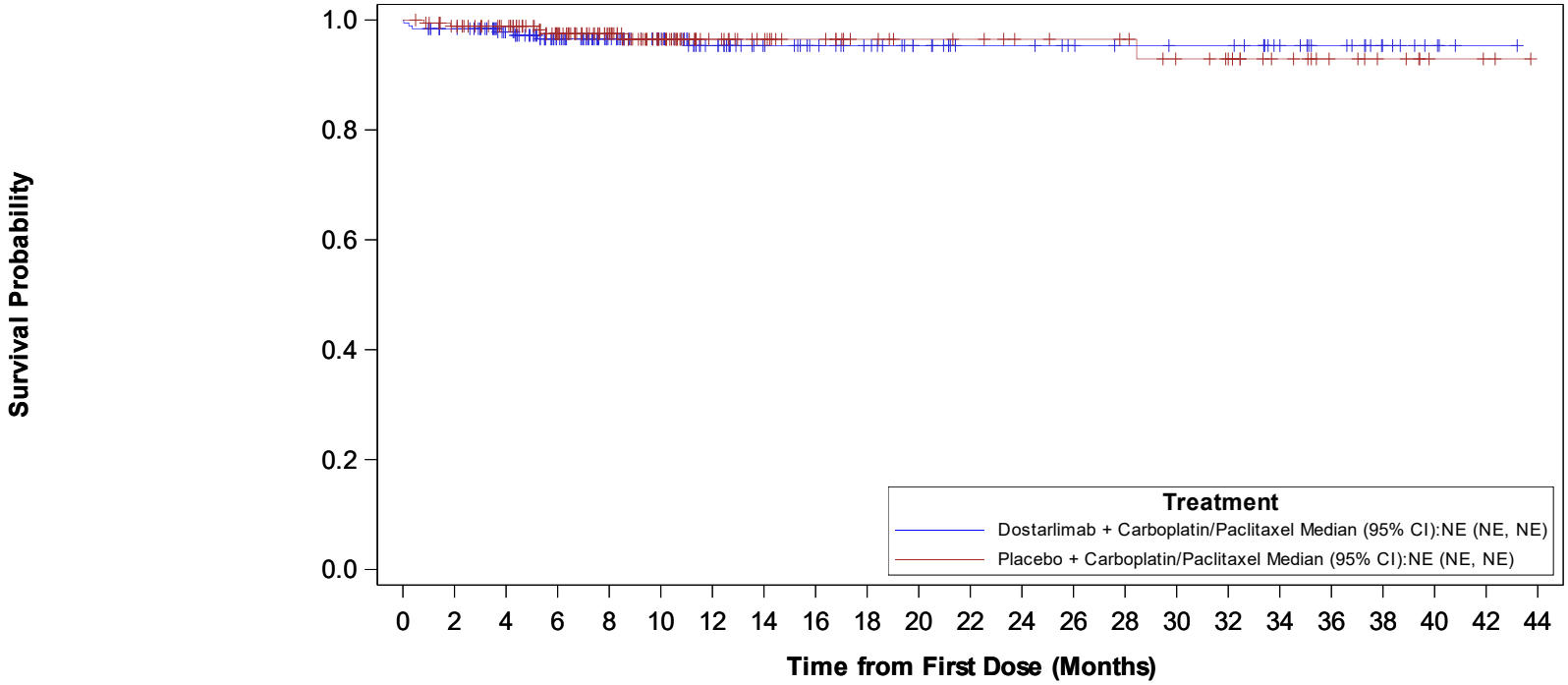


Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	177(5)	159(6)	133(6)	108(6)	89(7)	73(7)	58(7)	52(7)	47(7)	40(7)	32(7)	32(7)	28(8)	25(8)	24(8)	23(9)	16(9)	11(9)	6(9)	3(9)	1(9)	0(9)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	173(1)	158(3)	133(3)	104(3)	79(3)	57(3)	49(3)	43(3)	36(3)	34(3)	33(3)	29(4)	28(4)	27(4)	24(4)	22(4)	15(4)	11(4)	8(4)	4(4)	3(4)	0(4)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: General disorders and administration site conditions
Preferred Term: Non-cardiac chest pain



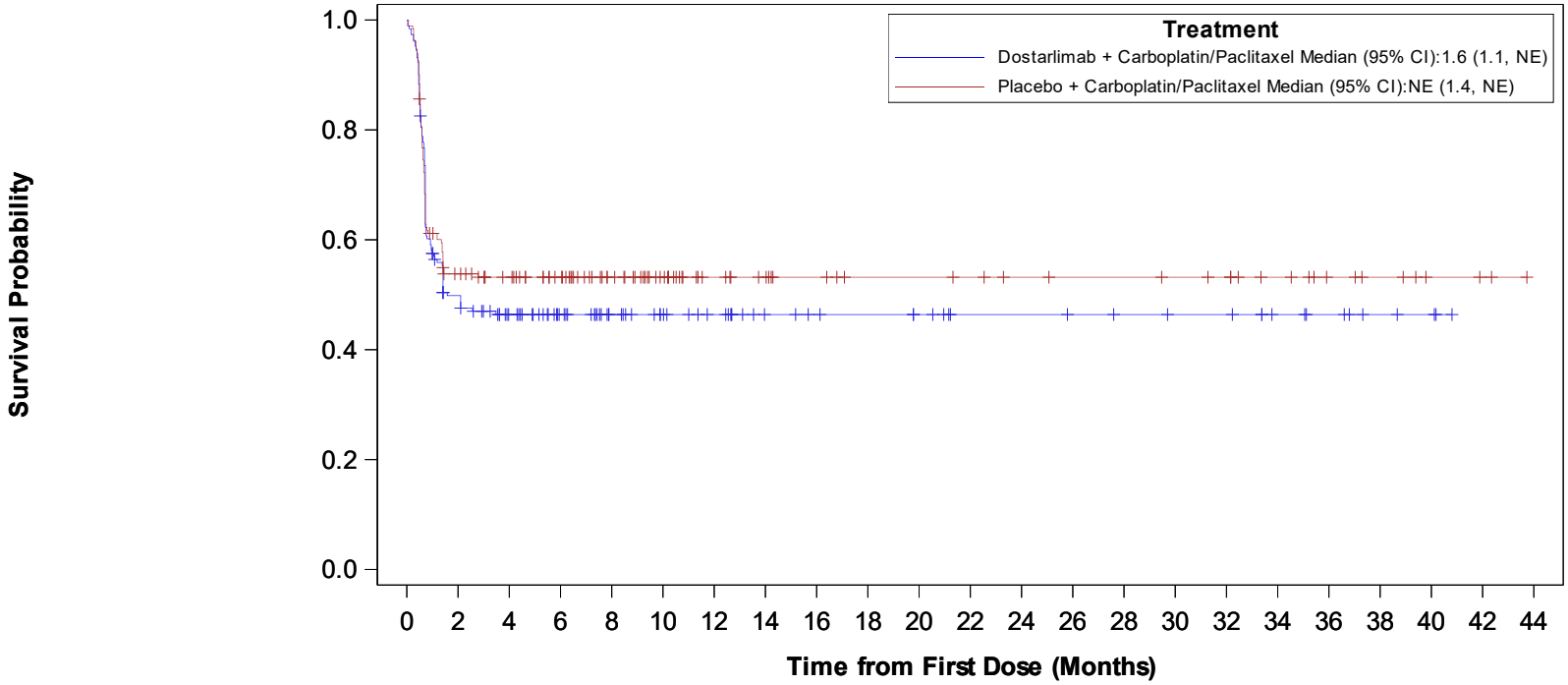
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	180(3)	162(4)	134(6)	108(6)	89(6)	72(7)	58(7)	52(7)	47(7)	40(7)	33(7)	33(7)	30(7)	28(7)	27(7)	27(7)	20(7)	15(7)	8(7)	4(7)	1(7)	0(7)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	172(2)	160(2)	132(4)	104(4)	78(5)	57(5)	49(5)	43(5)	37(5)	34(5)	33(5)	30(5)	29(5)	28(5)	24(6)	22(6)	15(6)	10(6)	7(6)	3(6)	2(6)	0(6)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Alopecia



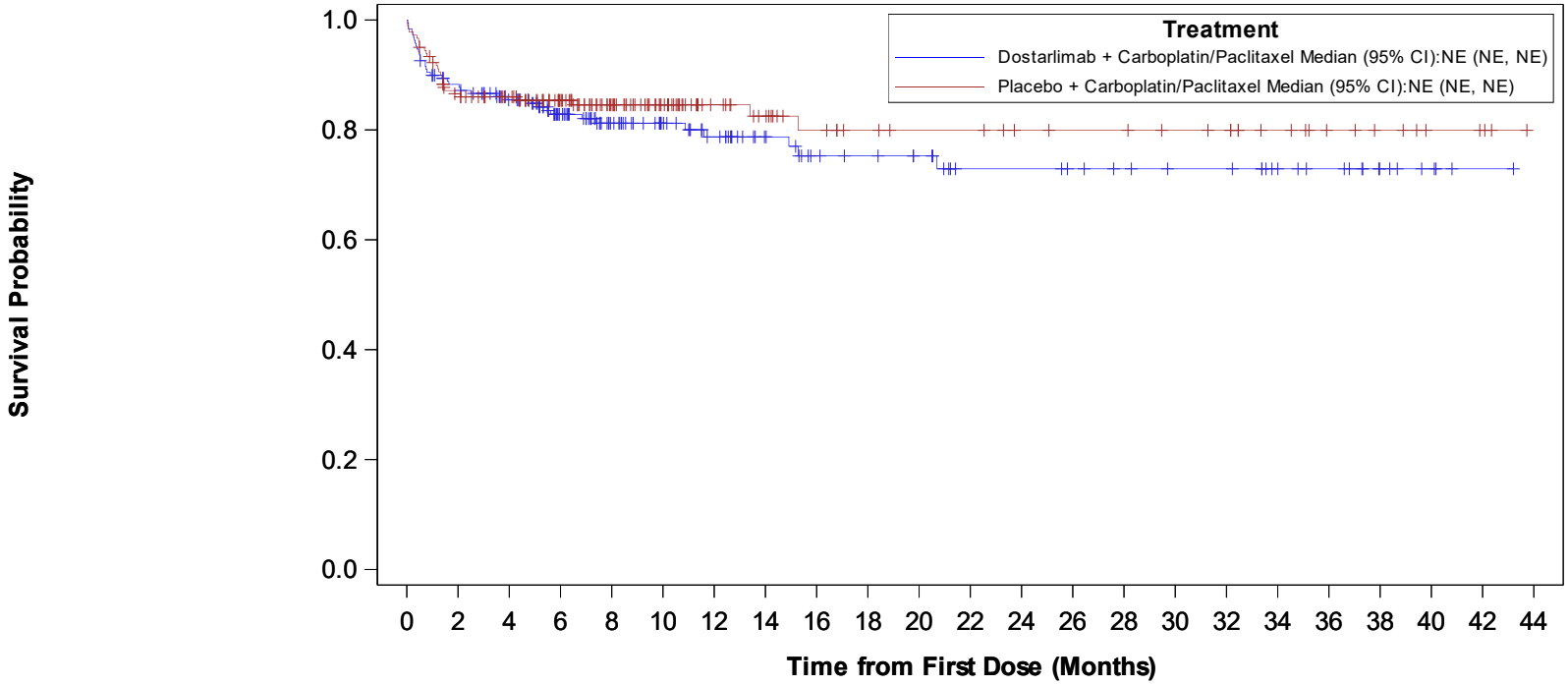
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	88(94)	71(100)	57(100)	45(100)	38(100)	33(100)	25(100)	23(100)	22(100)	20(100)	16(100)	16(100)	15(100)	14(100)	13(100)	13(100)	9(100)	7(100)	4(100)	3(100)	0(100)		
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	92(83)	83(84)	72(84)	57(84)	45(84)	33(84)	29(84)	25(84)	22(84)	22(84)	21(84)	19(84)	18(84)	18(84)	17(84)	16(84)	12(84)	8(84)	6(84)	3(84)	2(84)	0(84)	

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Pruritus



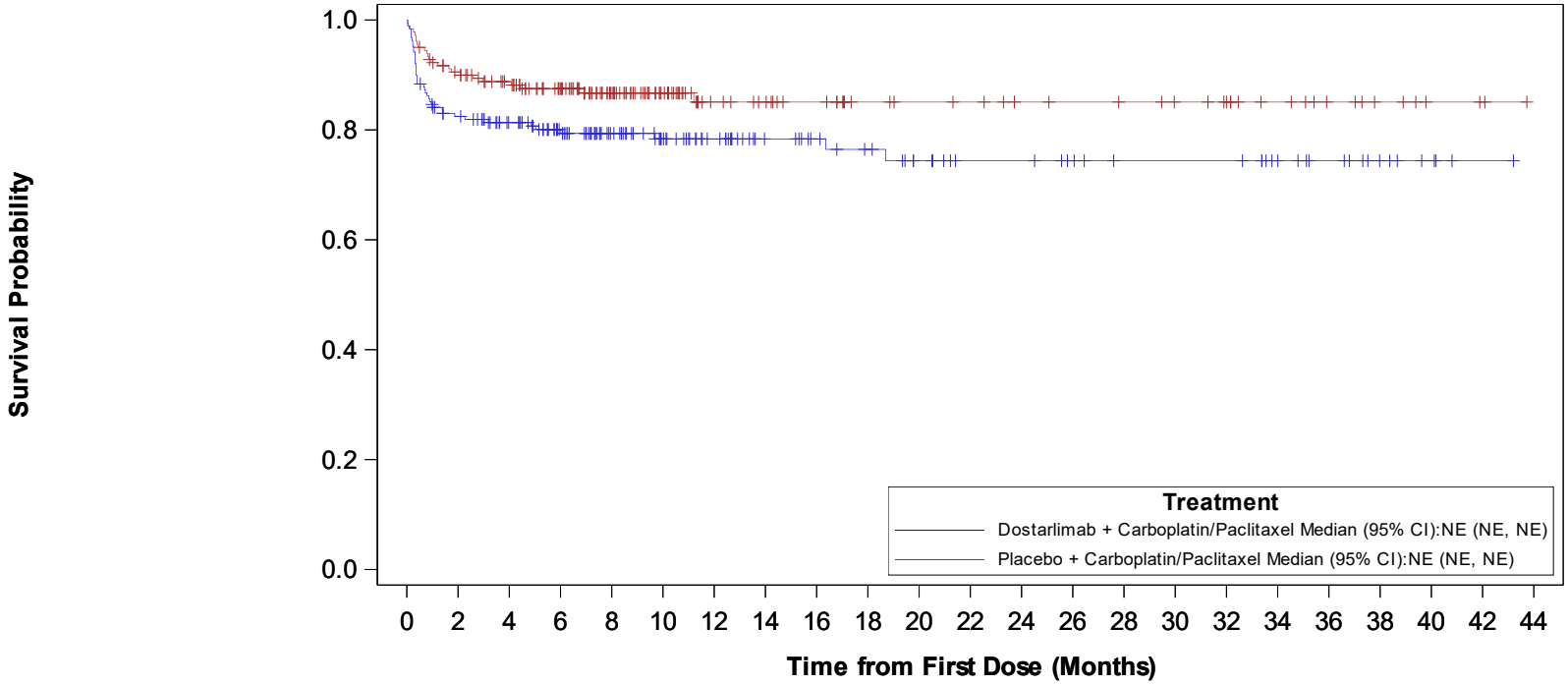
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	160(22)	142(27)	113(31)	88(33)	71(33)	60(35)	47(35)	39(37)	37(37)	34(37)	27(38)	27(38)	25(38)	23(38)	21(38)	21(38)	16(38)	13(38)	7(38)	4(38)	1(38)	0(38)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	150(24)	138(25)	113(26)	88(27)	67(27)	45(27)	38(28)	31(29)	27(29)	25(29)	25(29)	22(29)	21(29)	21(29)	19(29)	18(29)	13(29)	9(29)	7(29)	4(29)	3(29)	0(29)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash



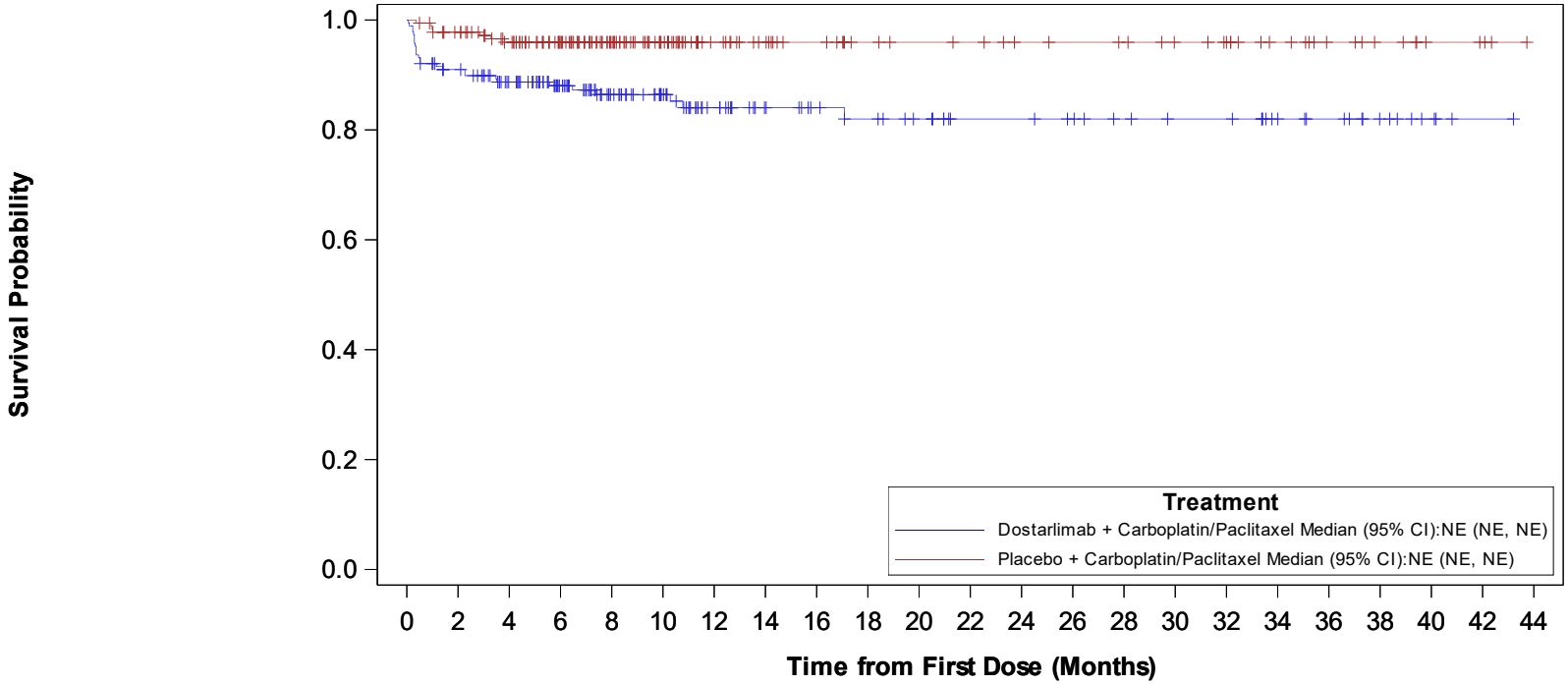
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	150(33)	134(35)	113(37)	90(38)	74(39)	61(39)	47(39)	42(39)	38(40)	32(41)	27(41)	27(41)	24(41)	21(41)	21(41)	21(41)	16(41)	12(41)	7(41)	4(41)	1(41)	0(41)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	158(17)	143(20)	121(22)	92(23)	68(23)	46(24)	42(24)	37(24)	30(24)	28(24)	27(24)	24(24)	23(24)	22(24)	20(24)	18(24)	13(24)	9(24)	6(24)	3(24)	2(24)	0(24)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular



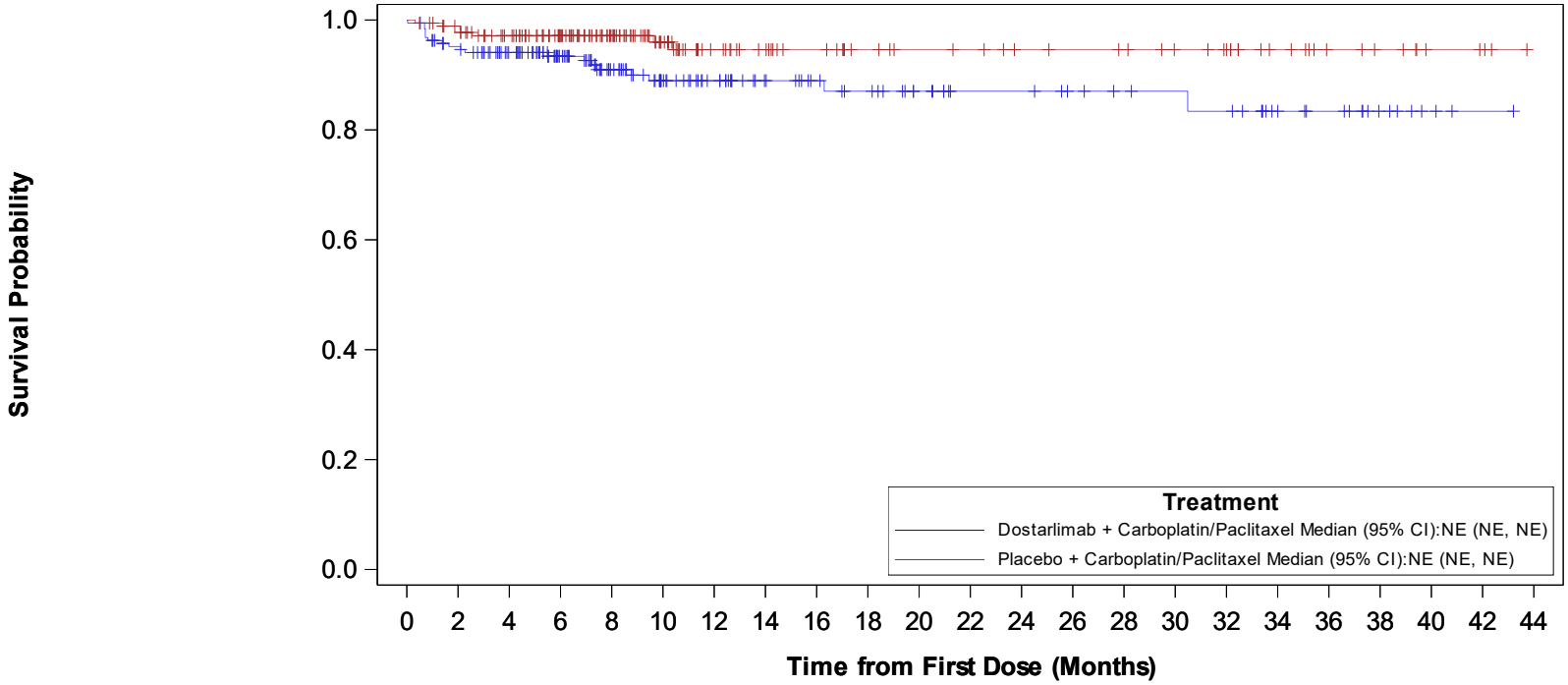
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	165(17)	146(21)	121(22)	95(24)	77(24)	59(26)	47(26)	42(26)	39(27)	35(27)	29(27)	29(27)	27(27)	24(27)	22(27)	22(27)	16(27)	13(27)	8(27)	4(27)	1(27)	0(27)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	170(4)	154(7)	129(7)	100(7)	77(7)	55(7)	47(7)	41(7)	35(7)	33(7)	32(7)	29(7)	28(7)	27(7)	24(7)	22(7)	16(7)	11(7)	8(7)	4(7)	3(7)	0(7)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin



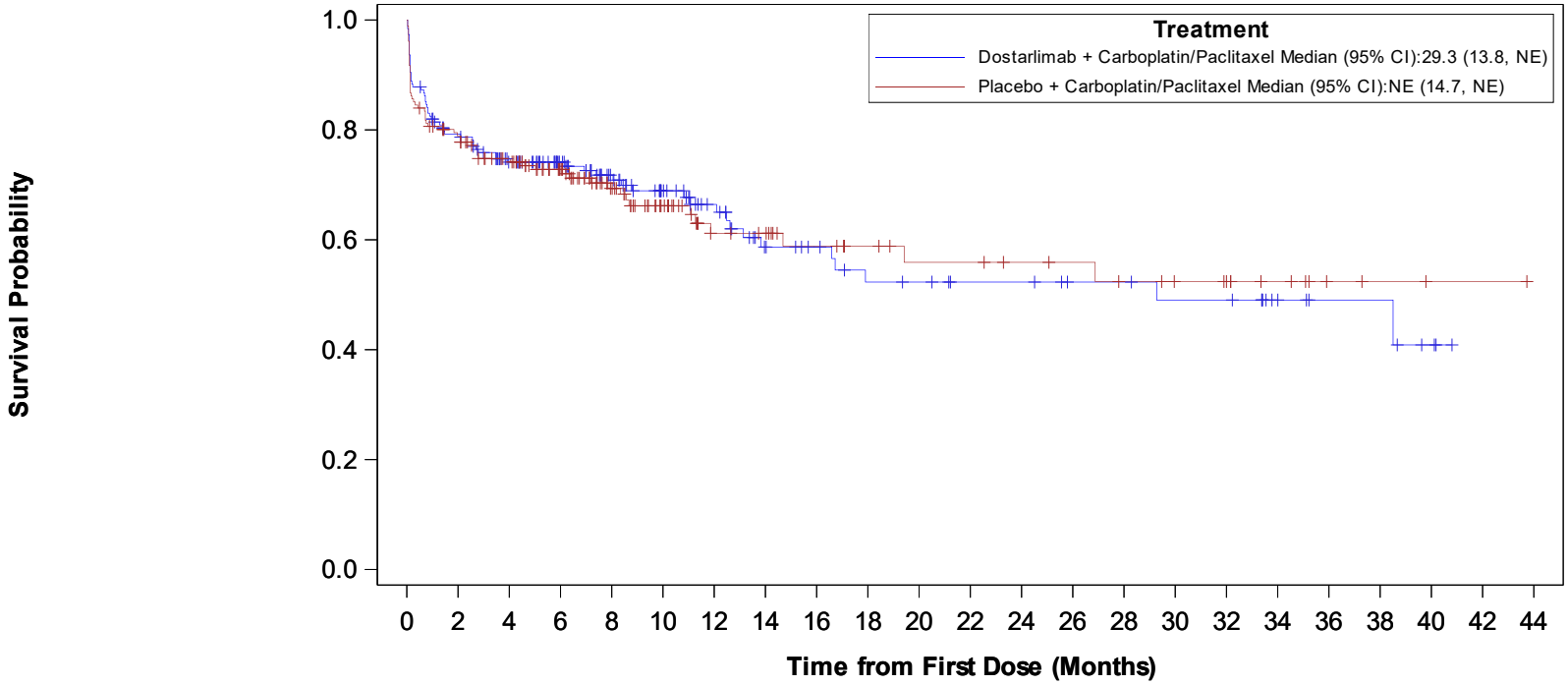
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	173(9)	155(11)	127(12)	99(15)	78(17)	66(17)	53(17)	47(17)	43(18)	36(18)	30(18)	30(18)	27(18)	25(18)	24(18)	23(19)	16(19)	13(19)	7(19)	3(19)	1(19)	0(19)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	172(2)	156(5)	131(5)	103(5)	76(6)	55(7)	48(7)	42(7)	36(7)	33(7)	32(7)	29(7)	28(7)	27(7)	24(7)	22(7)	15(7)	10(7)	8(7)	4(7)	3(7)	0(7)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

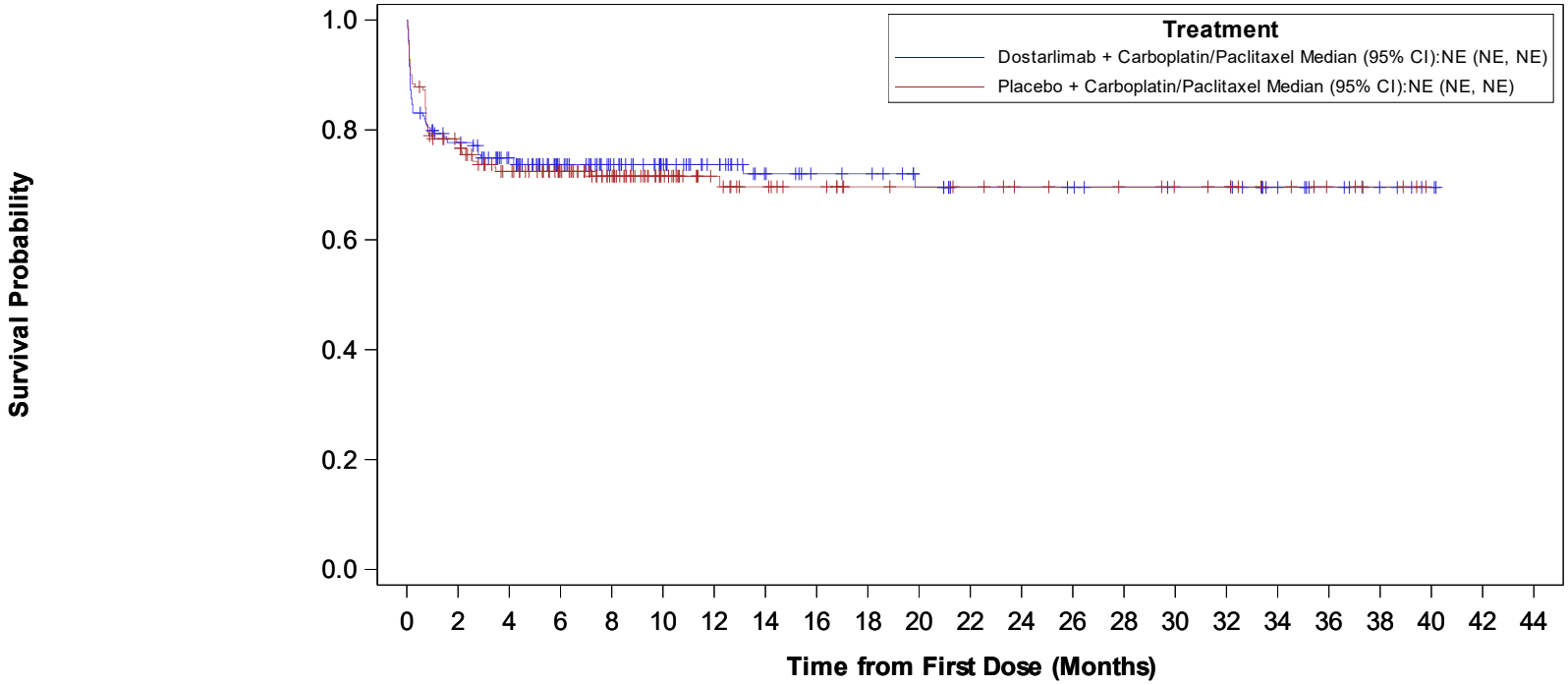
System Organ Class: Musculoskeletal and connective tissue disorders
Preferred Term: Arthralgia



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Musculoskeletal and connective tissue disorders
Preferred Term: Myalgia



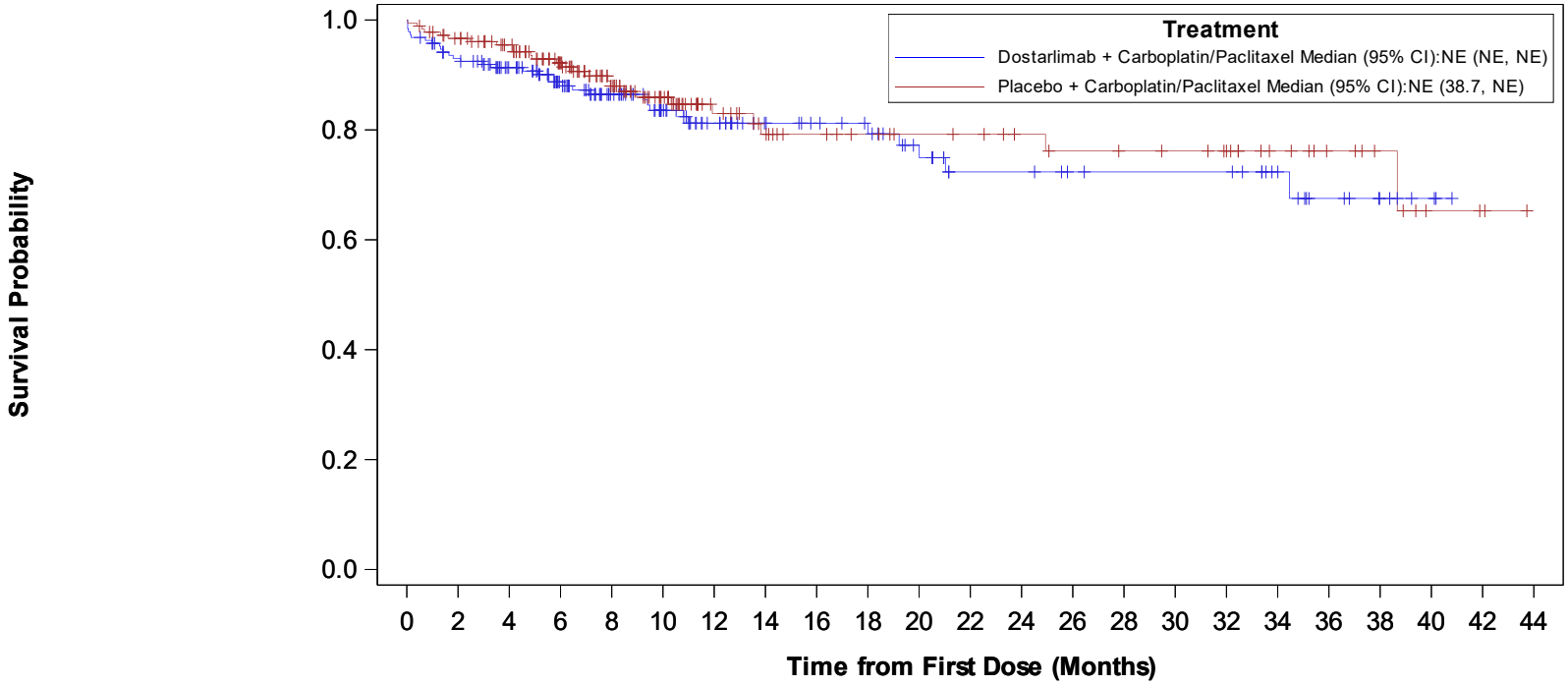
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	142(42)	123(47)	97(49)	81(49)	64(49)	52(49)	40(50)	35(50)	34(50)	28(51)	23(51)	23(51)	22(51)	20(51)	19(51)	19(51)	13(51)	9(51)	5(51)	2(51)	0(51)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	135(40)	114(49)	96(49)	75(50)	51(50)	37(50)	31(51)	27(51)	22(51)	21(51)	20(51)	17(51)	16(51)	15(51)	13(51)	12(51)	8(51)	5(51)	3(51)	0(51)	

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Musculoskeletal and connective tissue disorders
Preferred Term: Back pain



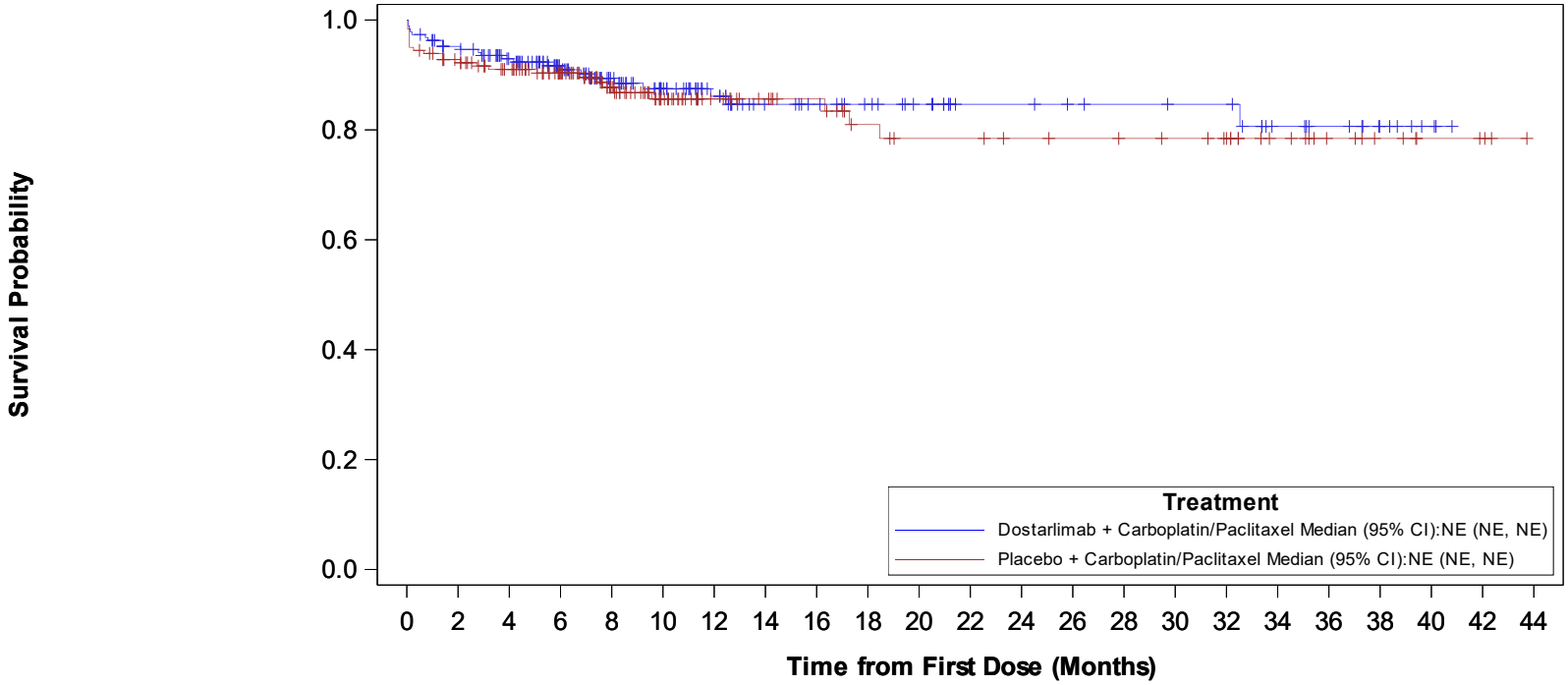
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	169(13)	149(16)	123(20)	98(23)	77(26)	61(28)	49(28)	45(28)	42(28)	34(30)	26(32)	26(32)	23(32)	22(32)	22(32)	22(32)	16(32)	10(33)	6(33)	3(33)	0(33)	
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	169(6)	155(8)	125(13)	95(18)	72(20)	49(22)	41(24)	36(24)	33(24)	30(24)	29(24)	26(24)	24(25)	23(25)	22(25)	20(25)	14(25)	10(25)	7(25)	3(26)	2(26)	0(26)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Musculoskeletal and connective tissue disorders
Preferred Term: Pain in extremity



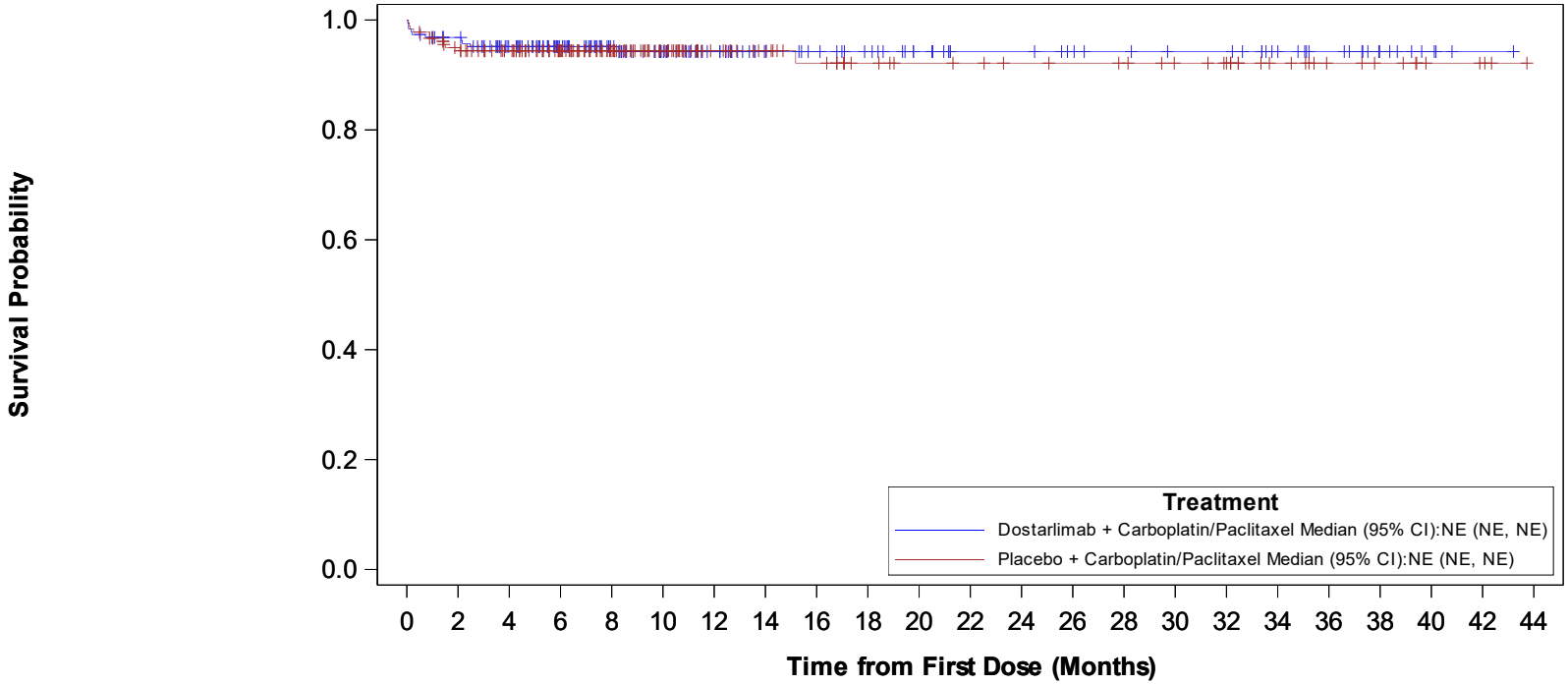
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	173(9)	154(13)	126(15)	99(18)	79(20)	63(21)	48(22)	44(22)	39(22)	34(22)	26(22)	26(22)	24(22)	23(22)	22(22)	22(22)	15(23)	12(23)	7(23)	3(23)	0(23)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	161(13)	146(16)	123(17)	93(20)	68(22)	50(22)	43(22)	39(22)	32(24)	29(25)	29(25)	27(25)	26(25)	25(25)	24(25)	22(25)	15(25)	10(25)	7(25)	4(25)	3(25)	0(25)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

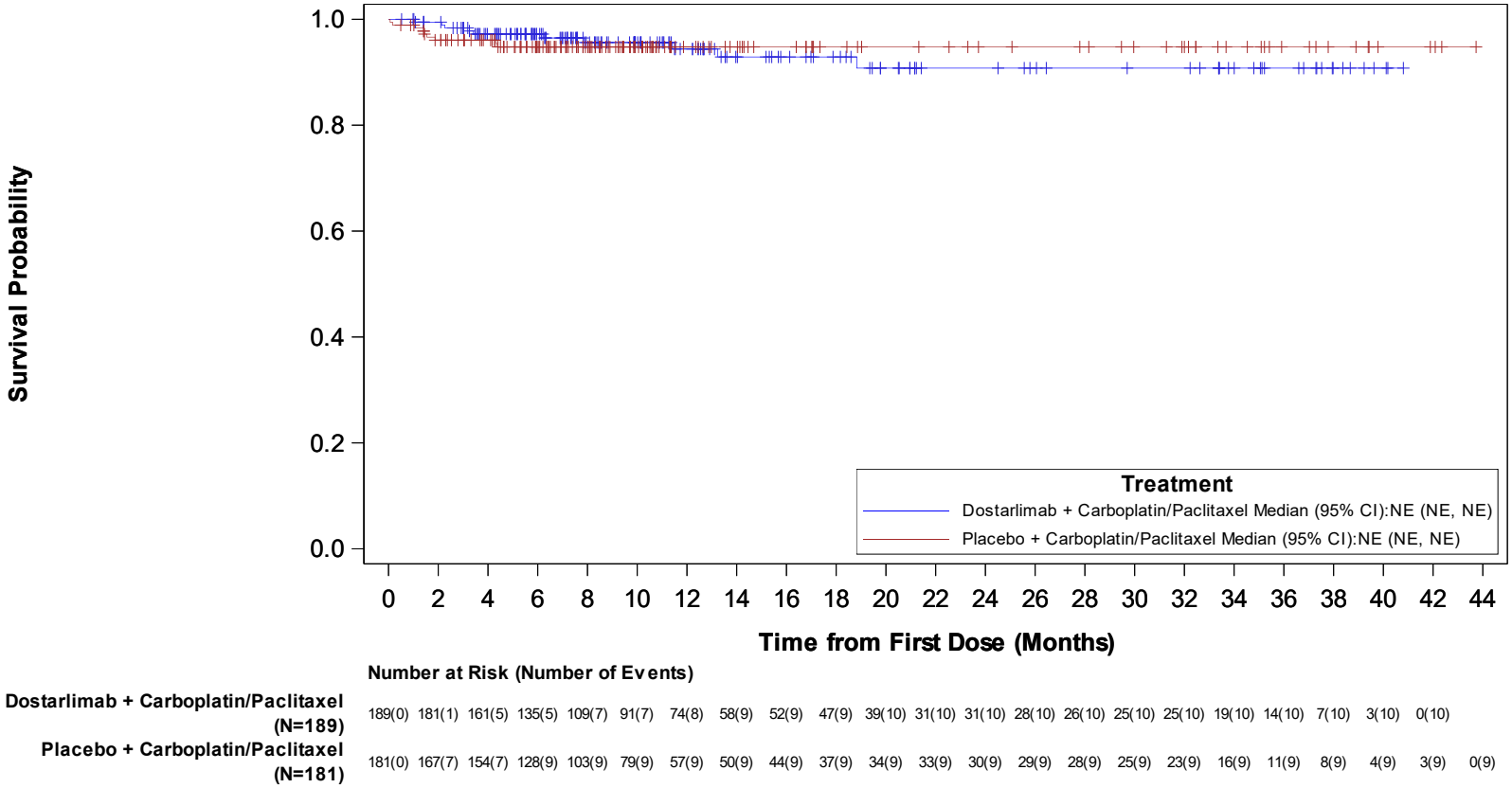
System Organ Class: Musculoskeletal and connective tissue disorders
Preferred Term: Bone pain



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

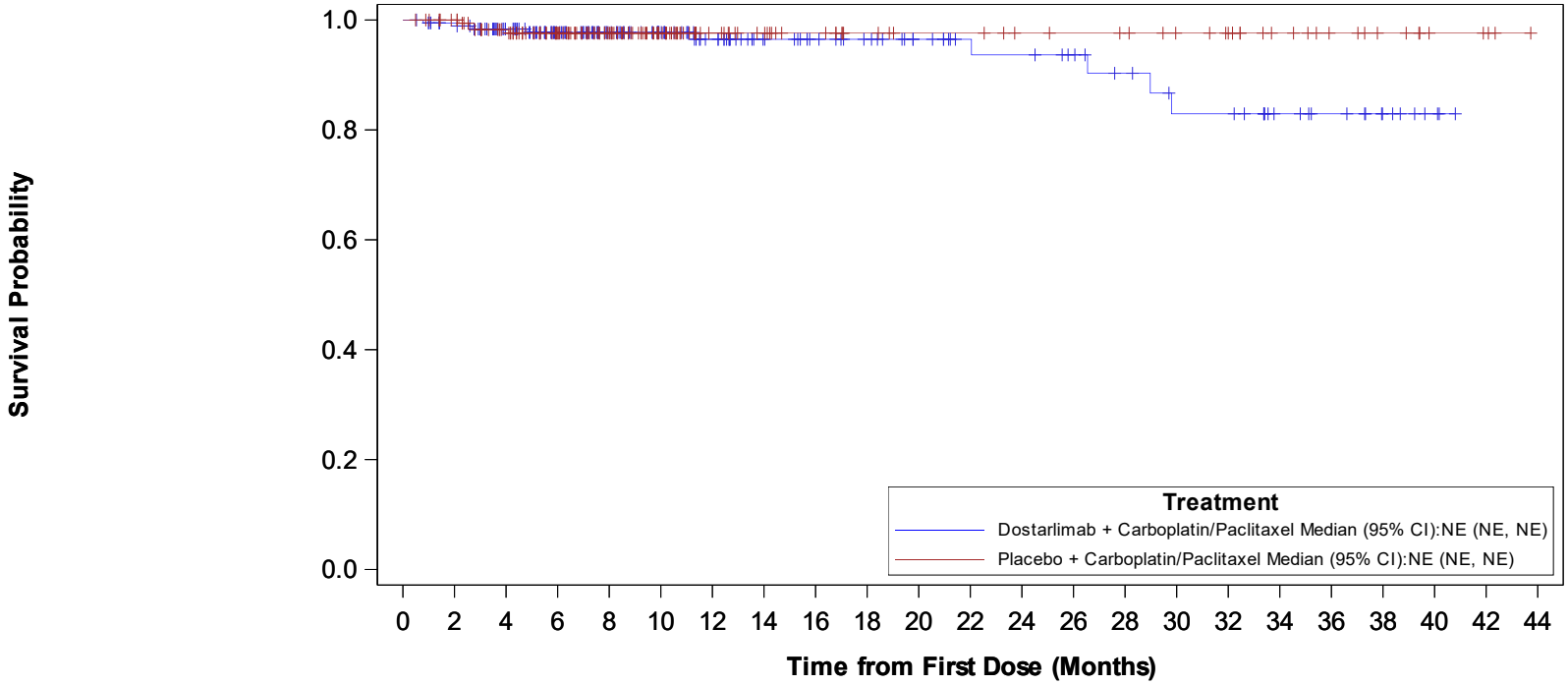
System Organ Class: Musculoskeletal and connective tissue disorders
Preferred Term: Muscular weakness



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Musculoskeletal and connective tissue disorders
Preferred Term: Muscle spasms



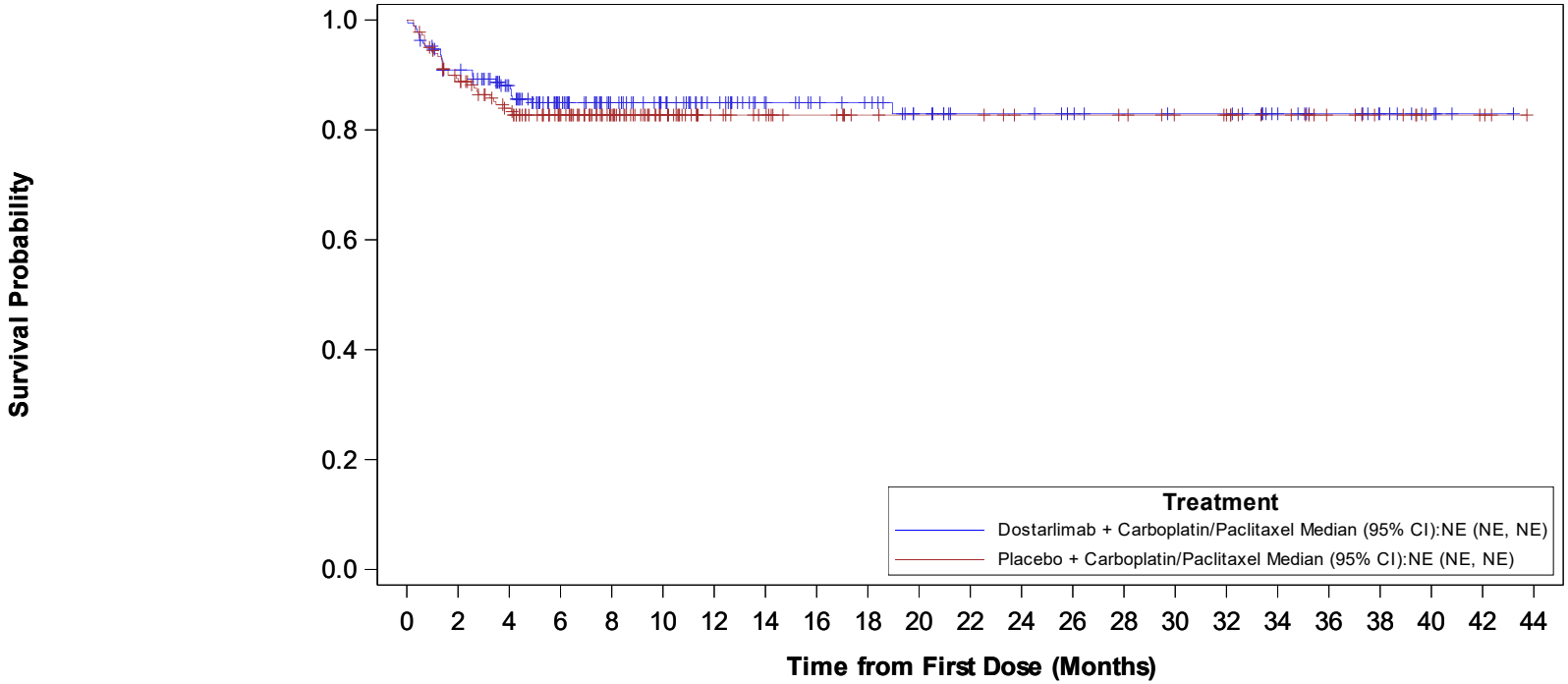
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	181(1)	162(3)	134(4)	108(4)	89(4)	73(5)	58(5)	52(5)	47(5)	40(5)	34(5)	33(6)	30(6)	26(7)	22(9)	22(9)	15(9)	12(9)	7(9)	3(9)	0(9)	
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	174(0)	158(3)	131(4)	102(4)	76(4)	54(4)	47(4)	41(4)	35(4)	32(4)	32(4)	29(4)	28(4)	27(4)	24(4)	22(4)	15(4)	11(4)	8(4)	4(4)	3(4)	0(4)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Neutrophil count decreased



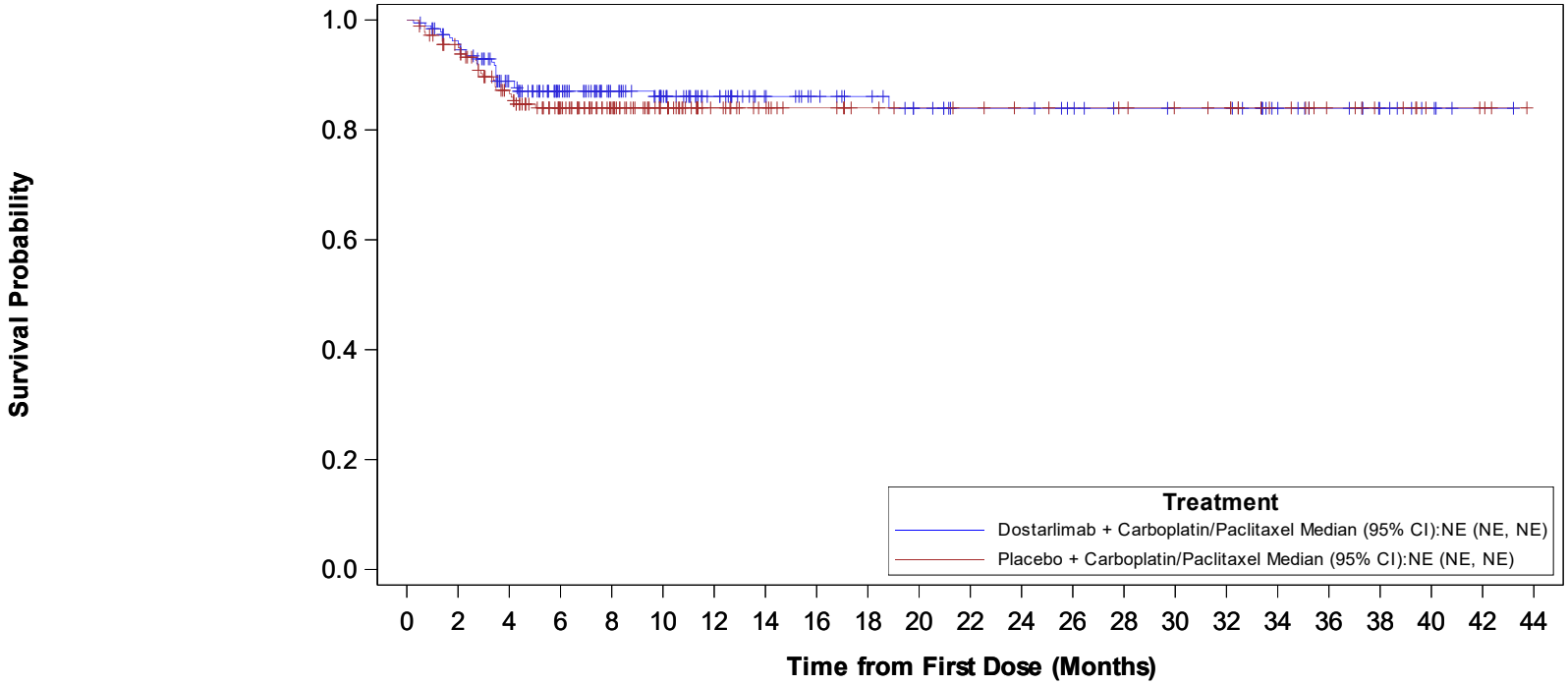
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	165(17)	143(22)	113(27)	93(27)	80(27)	66(27)	53(27)	48(27)	45(27)	37(28)	31(28)	31(28)	28(28)	26(28)	25(28)	25(28)	18(28)	13(28)	8(28)	4(28)	1(28)	0(28)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	155(19)	135(28)	110(30)	85(30)	61(30)	45(30)	40(30)	35(30)	30(30)	29(30)	29(30)	26(30)	26(30)	25(30)	22(30)	21(30)	16(30)	11(30)	8(30)	4(30)	3(30)	0(30)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Platelet count decreased



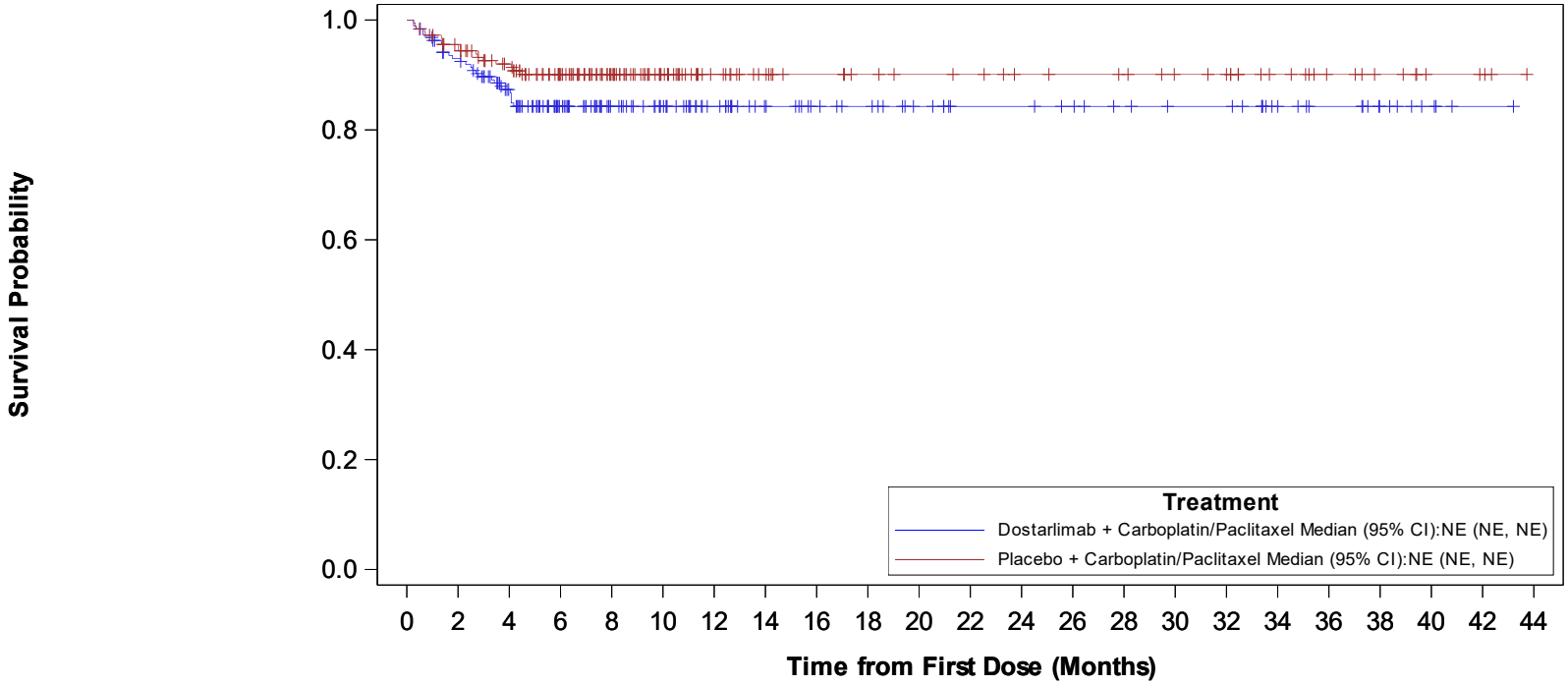
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	175(7)	146(20)	119(23)	97(23)	82(24)	66(24)	52(24)	46(24)	42(24)	36(25)	31(25)	31(25)	28(25)	25(25)	24(25)	24(25)	17(25)	13(25)	8(25)	4(25)	1(25)	0(25)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	166(8)	139(22)	110(27)	87(27)	66(27)	49(27)	41(27)	36(27)	32(27)	30(27)	29(27)	27(27)	26(27)	25(27)	23(27)	22(27)	16(27)	11(27)	8(27)	4(27)	3(27)	0(27)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: White blood cell count decreased



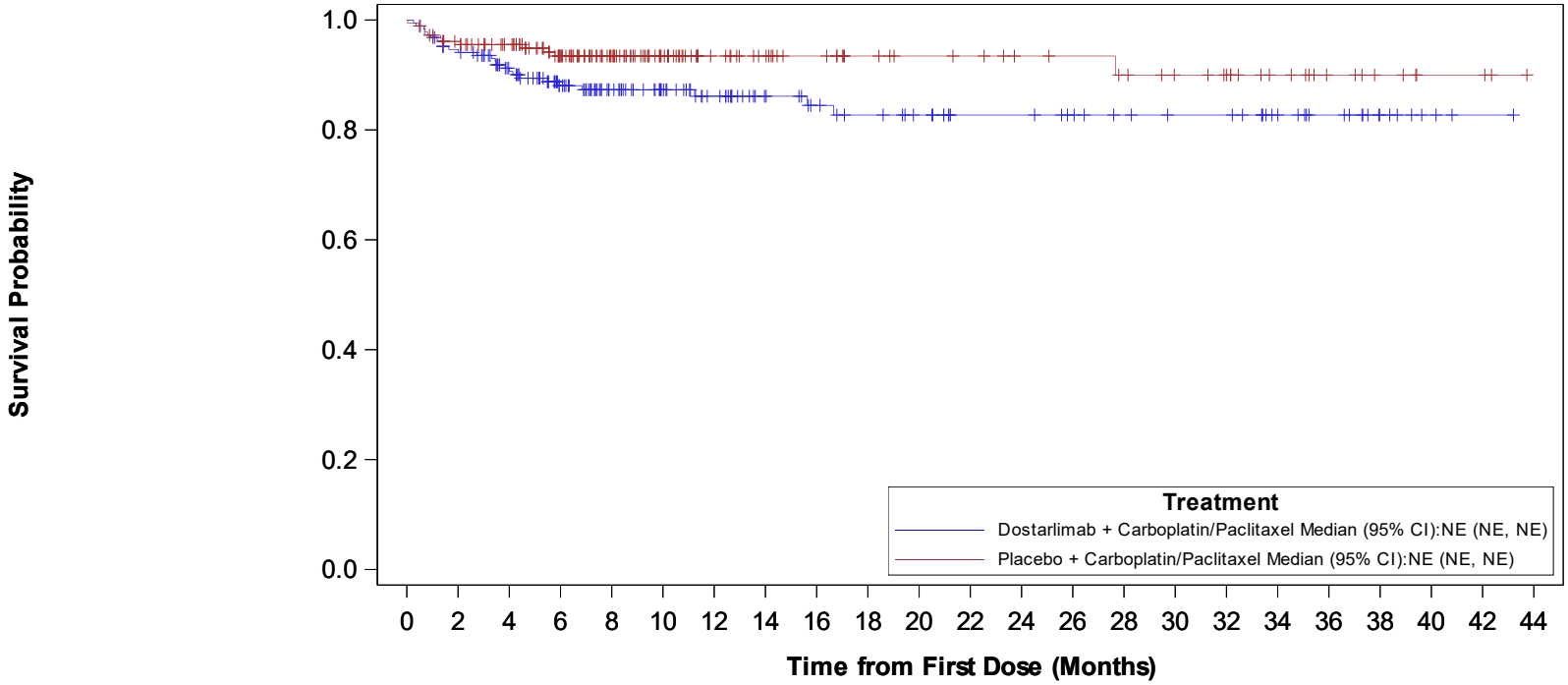
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	169(13)	143(23)	112(28)	90(28)	78(28)	63(28)	51(28)	45(28)	42(28)	36(28)	31(28)	31(28)	29(28)	26(28)	24(28)	24(28)	17(28)	13(28)	8(28)	4(28)	1(28)	0(28)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	166(8)	148(14)	120(17)	93(17)	69(17)	51(17)	43(17)	38(17)	35(17)	33(17)	32(17)	29(17)	28(17)	27(17)	24(17)	23(17)	16(17)	11(17)	8(17)	4(17)	3(17)	0(17)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased



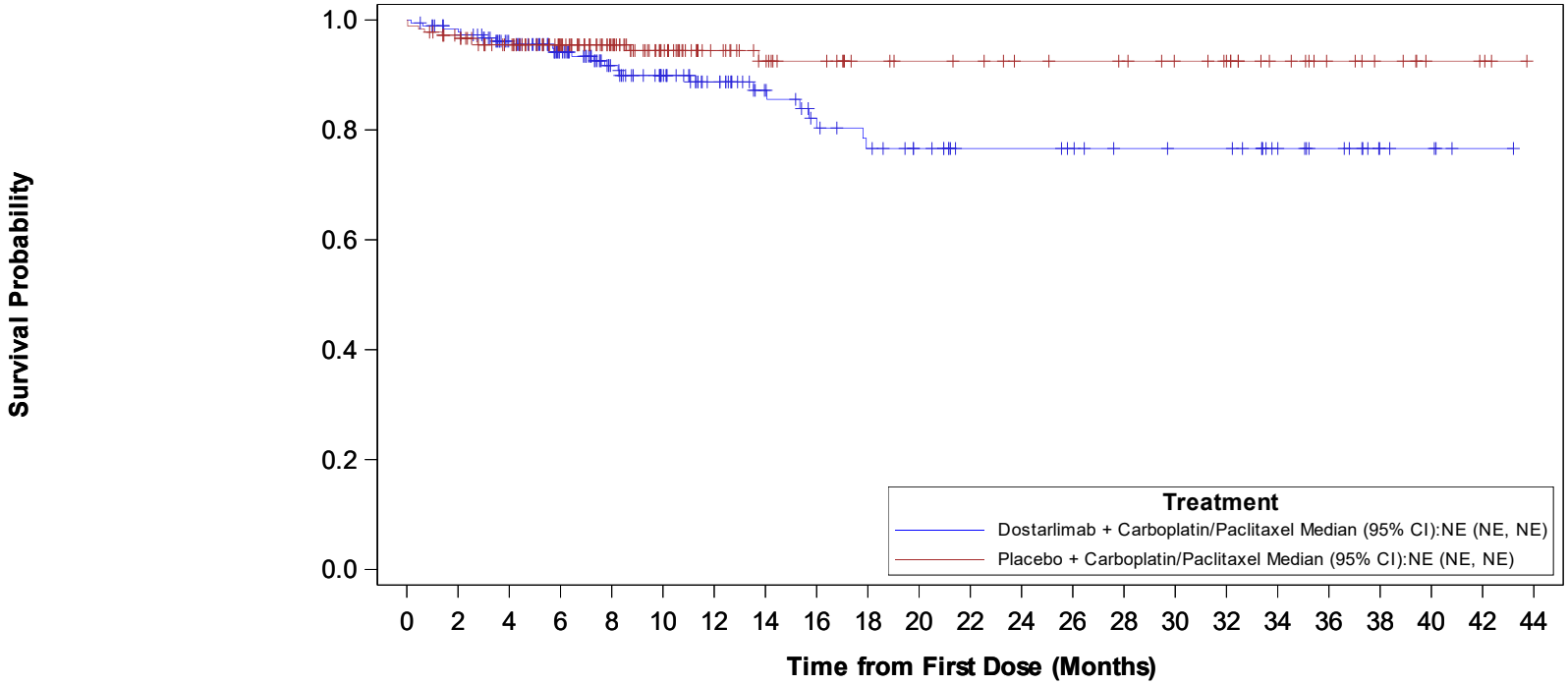
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	173(10)	151(16)	123(21)	99(22)	82(22)	69(23)	55(23)	49(24)	45(25)	41(25)	34(25)	34(25)	31(25)	28(25)	26(25)	26(25)	19(25)	14(25)	7(25)	3(25)	1(25)	0(25)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	167(7)	153(8)	124(11)	96(11)	72(11)	54(11)	47(11)	41(11)	35(11)	32(11)	31(11)	28(11)	27(11)	25(12)	22(12)	20(12)	14(12)	9(12)	6(12)	3(12)	3(12)	0(12)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased



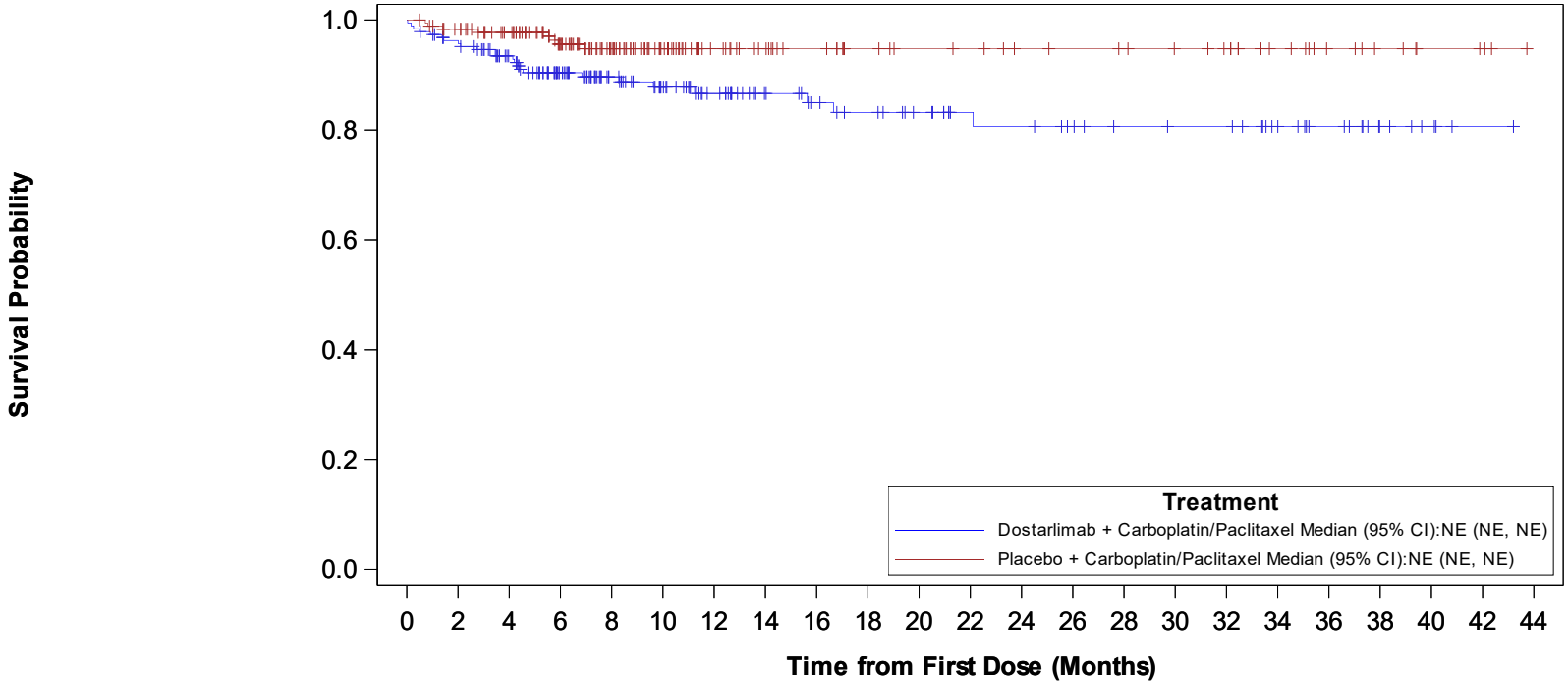
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	179(3)	158(7)	129(10)	102(13)	85(15)	69(16)	54(17)	46(21)	41(23)	36(23)	29(23)	29(23)	27(23)	24(23)	23(23)	23(23)	16(23)	12(23)	5(23)	4(23)	1(23)	0(23)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	170(5)	155(8)	129(8)	102(8)	77(9)	56(9)	47(10)	42(10)	36(10)	34(10)	33(10)	30(10)	29(10)	28(10)	25(10)	23(10)	16(10)	11(10)	8(10)	4(10)	3(10)	0(10)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased



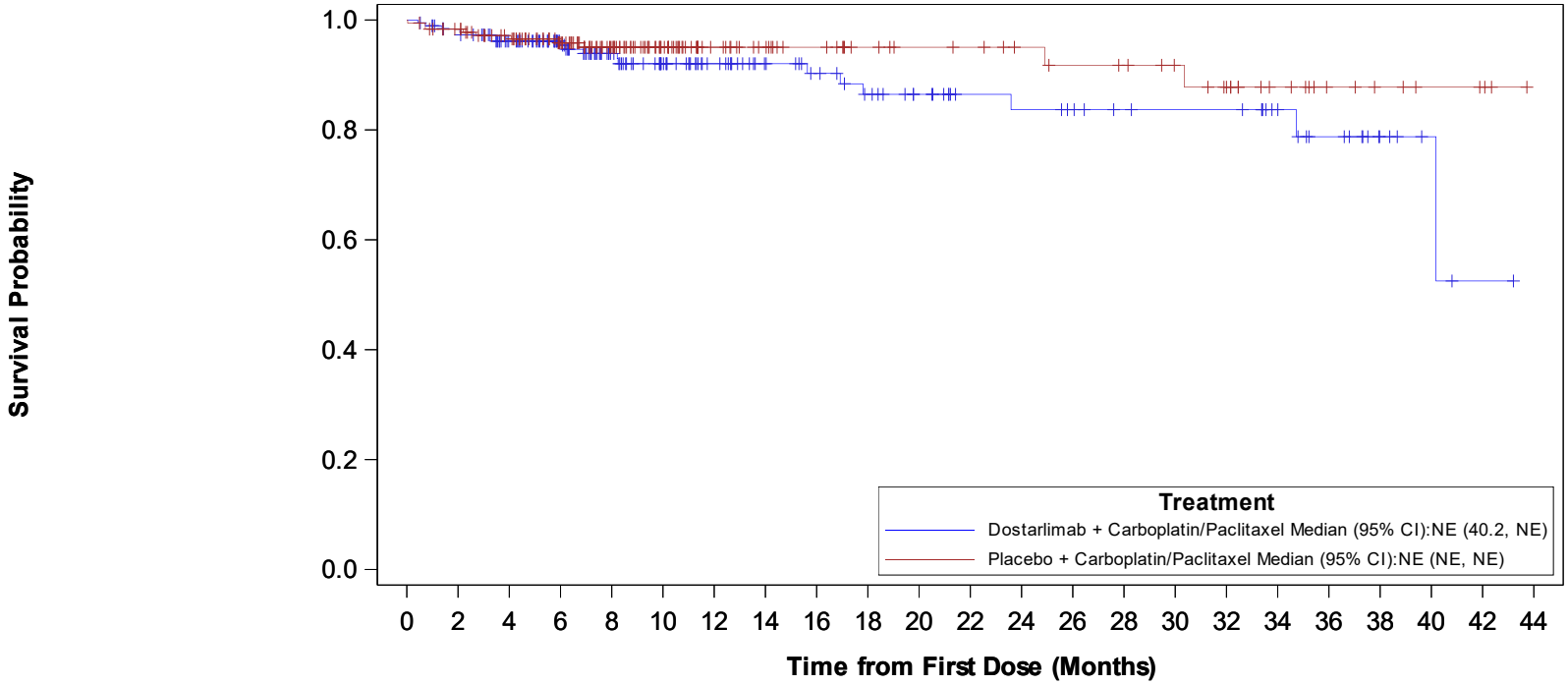
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	176(7)	155(12)	126(17)	100(18)	84(20)	69(21)	55(21)	49(22)	45(23)	40(23)	33(23)	32(24)	29(24)	26(24)	25(24)	25(24)	19(24)	14(24)	7(24)	4(24)	1(24)	0(24)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	171(3)	157(4)	129(7)	100(8)	75(8)	54(8)	46(8)	40(8)	34(8)	31(8)	30(8)	27(8)	26(8)	25(8)	23(8)	21(8)	15(8)	10(8)	7(8)	4(8)	3(8)	0(8)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Amylase increased



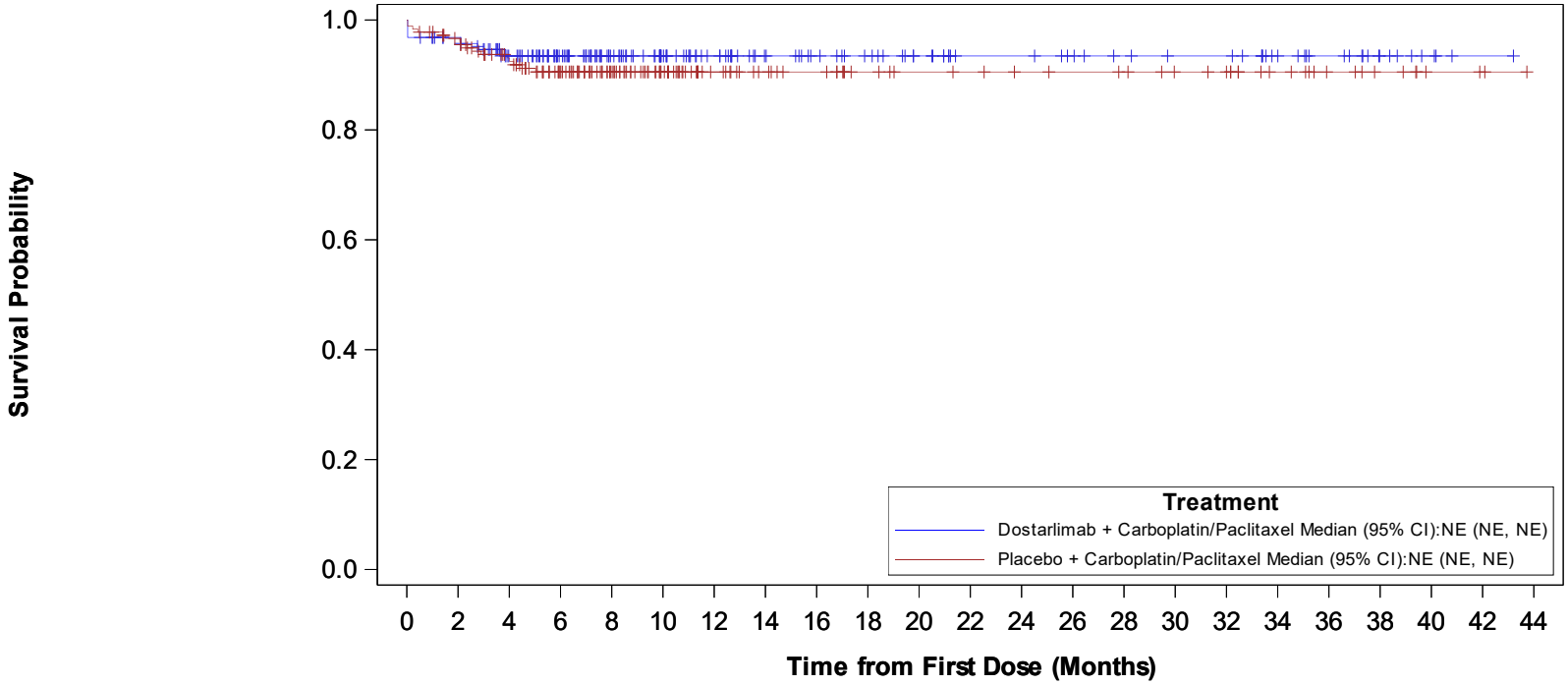
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	179(3)	159(7)	131(7)	102(10)	83(12)	68(12)	56(12)	50(13)	44(15)	38(15)	31(15)	30(16)	28(16)	25(16)	24(16)	24(16)	18(16)	13(17)	6(17)	3(17)	1(18)	0(18)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	172(3)	158(5)	131(7)	103(8)	77(8)	56(8)	48(8)	42(8)	36(8)	33(8)	32(8)	29(8)	27(9)	26(9)	23(9)	20(10)	13(10)	8(10)	6(10)	4(10)	3(10)	0(10)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Lymphocyte count decreased



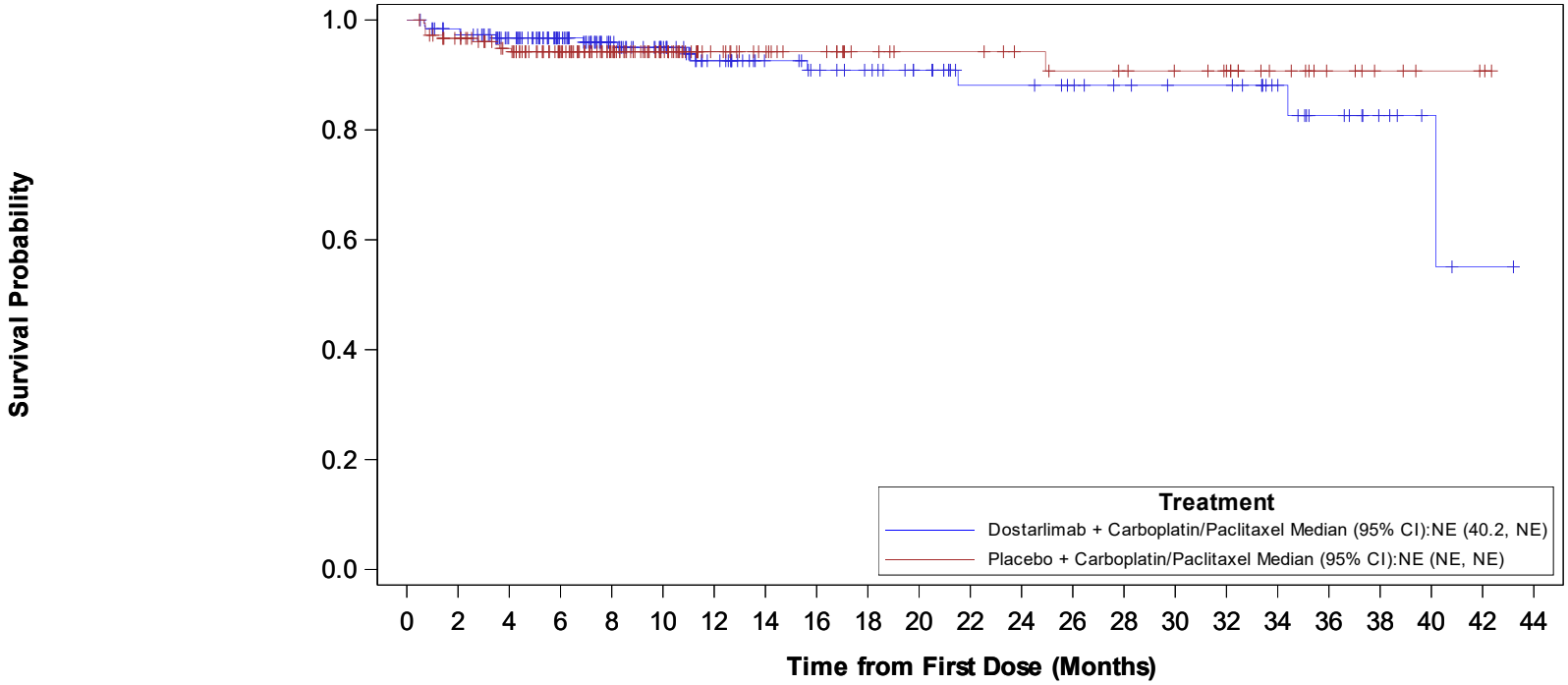
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	177(6)	156(12)	132(12)	107(12)	88(12)	74(12)	61(12)	55(12)	50(12)	43(12)	35(12)	35(12)	32(12)	29(12)	27(12)	27(12)	20(12)	15(12)	8(12)	4(12)	1(12)	0(12)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	168(6)	149(12)	123(16)	97(16)	74(16)	53(16)	45(16)	41(16)	34(16)	31(16)	30(16)	28(16)	27(16)	26(16)	23(16)	22(16)	15(16)	10(16)	7(16)	3(16)	2(16)	0(16)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Lipase increased



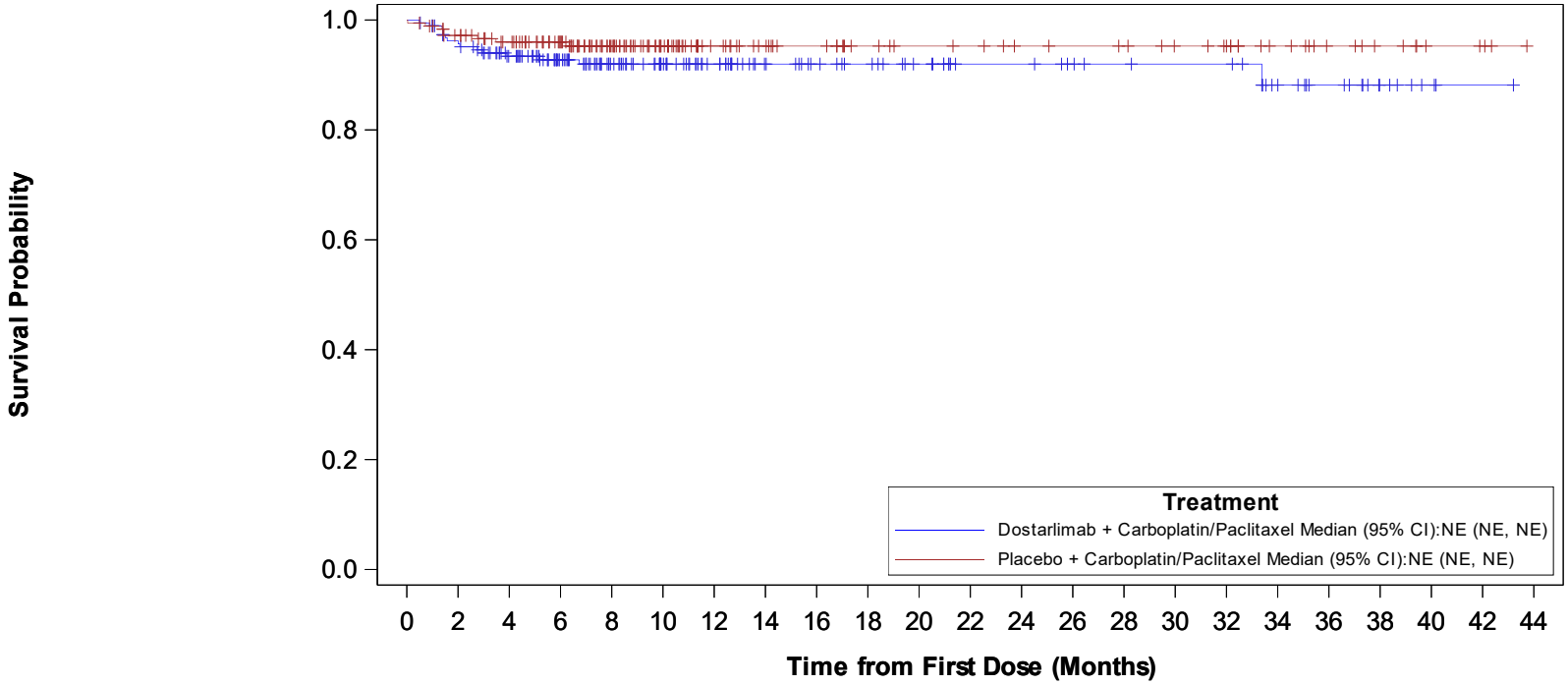
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	179(3)	159(6)	131(6)	104(7)	86(8)	69(10)	56(10)	51(11)	47(11)	41(11)	32(12)	32(12)	29(12)	26(12)	24(12)	24(12)	17(12)	11(13)	6(13)	3(13)	1(14)	0(14)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	168(6)	153(9)	126(10)	99(10)	74(10)	53(10)	45(10)	40(10)	33(10)	30(10)	30(10)	27(10)	25(11)	24(11)	22(11)	20(11)	13(11)	8(11)	5(11)	3(11)	2(11)	0(11)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Weight decreased



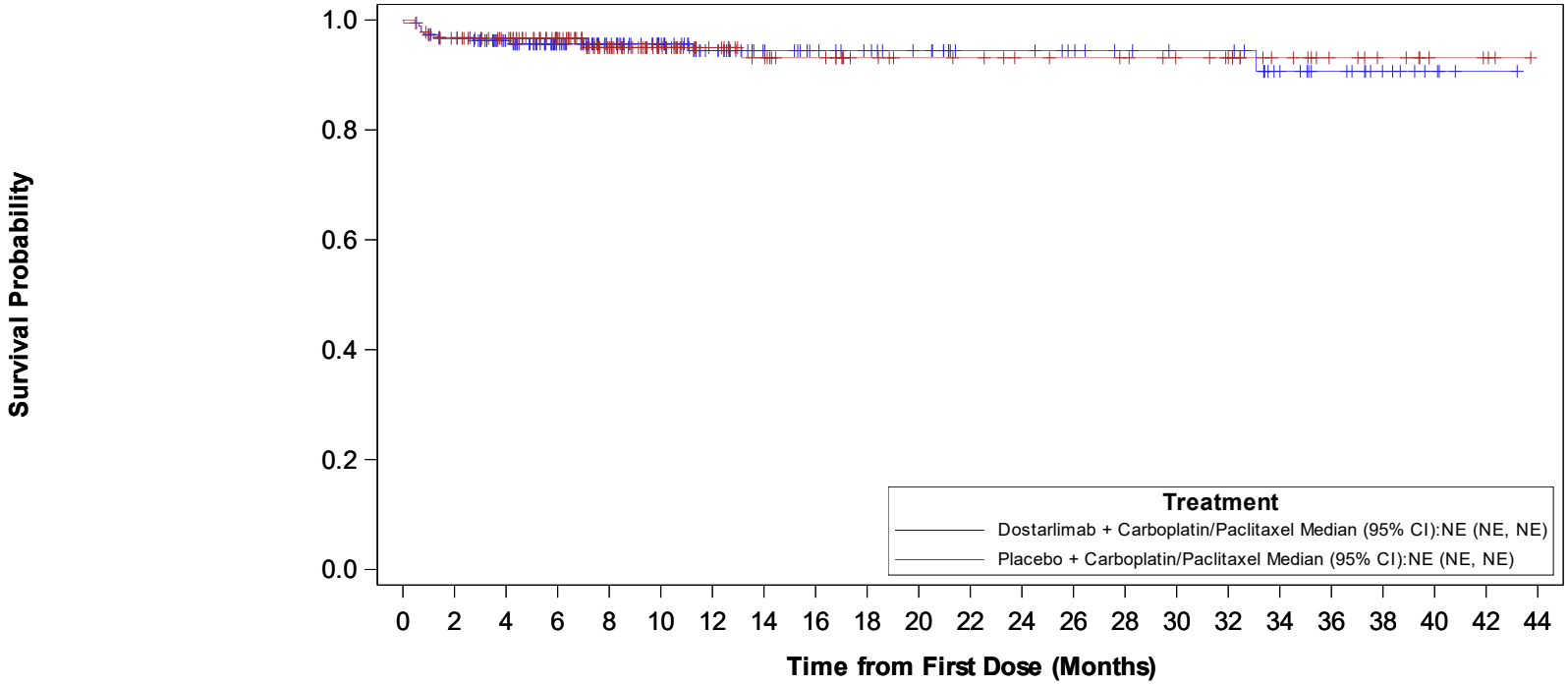
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	175(7)	154(12)	128(13)	104(14)	86(14)	71(14)	56(14)	50(14)	46(14)	40(14)	32(14)	32(14)	29(14)	27(14)	26(14)	26(14)	19(15)	14(15)	7(15)	3(15)	1(15)	0(15)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	169(5)	156(7)	134(7)	104(8)	79(8)	57(8)	49(8)	44(8)	37(8)	34(8)	33(8)	30(8)	29(8)	28(8)	25(8)	23(8)	16(8)	11(8)	8(8)	4(8)	3(8)	0(8)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood alkaline phosphatase increased



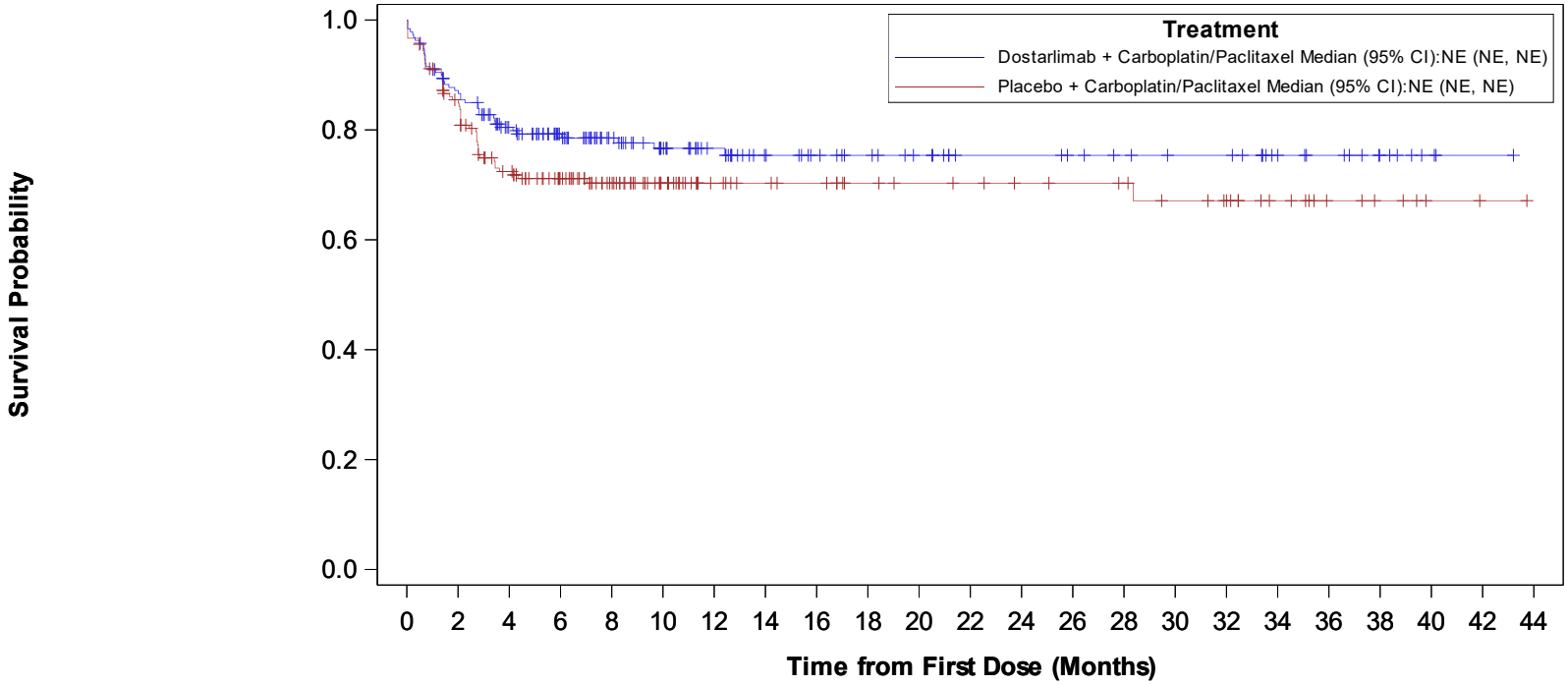
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	176(6)	158(7)	131(8)	106(8)	88(8)	72(9)	57(9)	51(9)	47(9)	43(9)	35(9)	35(9)	32(9)	29(9)	27(9)	27(9)	19(10)	14(10)	8(10)	4(10)	1(10)	0(10)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	169(6)	156(6)	130(6)	100(8)	76(8)	57(8)	49(9)	44(9)	37(9)	34(9)	33(9)	30(9)	29(9)	28(9)	25(9)	23(9)	16(9)	11(9)	8(9)	4(9)	3(9)	0(9)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypomagnesaemia



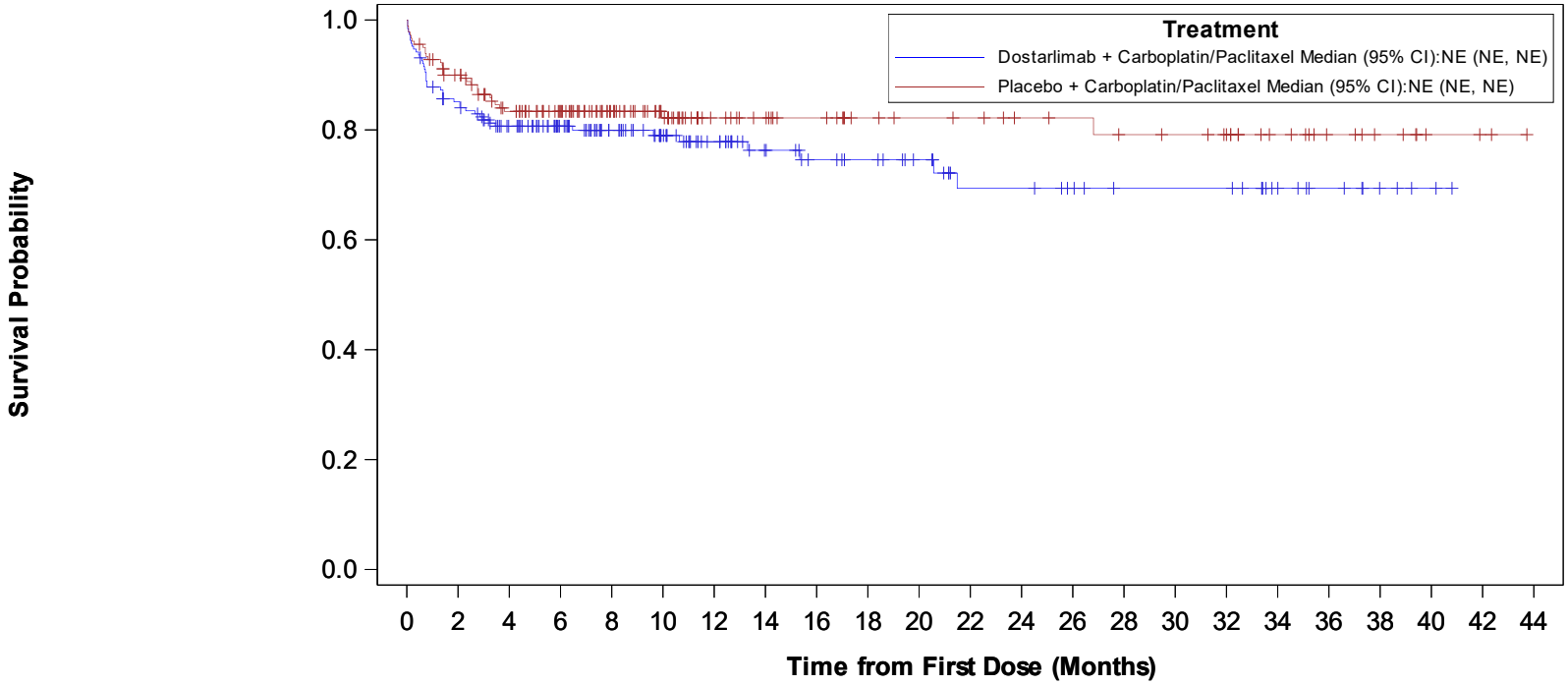
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	159(24)	133(36)	110(38)	88(39)	72(41)	60(41)	47(42)	42(42)	38(42)	34(42)	28(42)	28(42)	26(42)	24(42)	22(42)	22(42)	15(42)	12(42)	7(42)	3(42)	1(42)	0(42)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	148(26)	116(48)	95(50)	76(51)	57(51)	41(51)	37(51)	35(51)	30(51)	28(51)	27(51)	25(51)	24(51)	23(51)	20(52)	18(52)	12(52)	7(52)	5(52)	2(52)	1(52)	0(52)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Decreased appetite



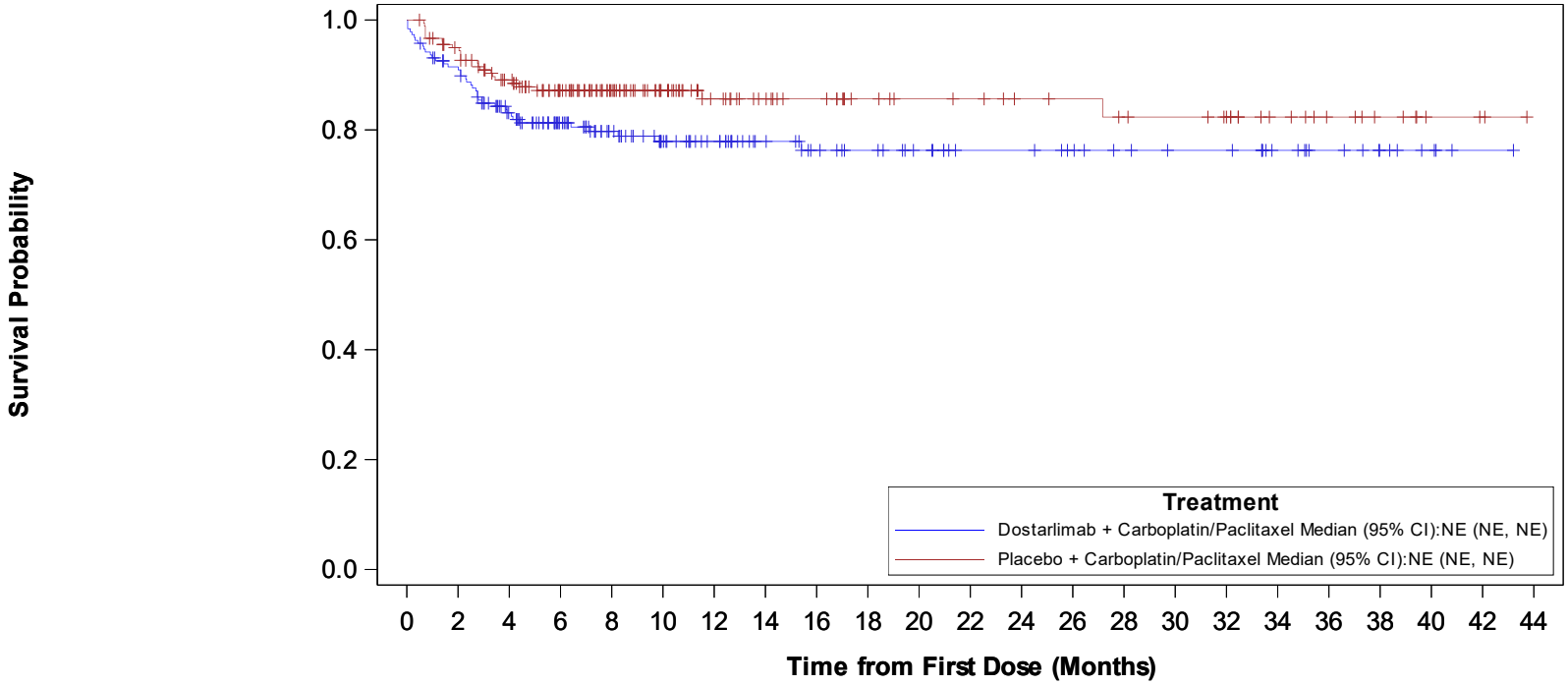
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	156(28)	135(36)	113(36)	92(37)	75(38)	60(39)	47(40)	41(41)	38(41)	33(41)	25(43)	25(43)	22(43)	19(43)	19(43)	19(43)	12(43)	8(43)	4(43)	2(43)	0(43)	
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	156(18)	134(29)	115(29)	89(29)	69(30)	50(30)	45(30)	40(30)	34(30)	32(30)	31(30)	28(30)	27(30)	25(31)	24(31)	22(31)	15(31)	10(31)	7(31)	3(31)	2(31)	0(31)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

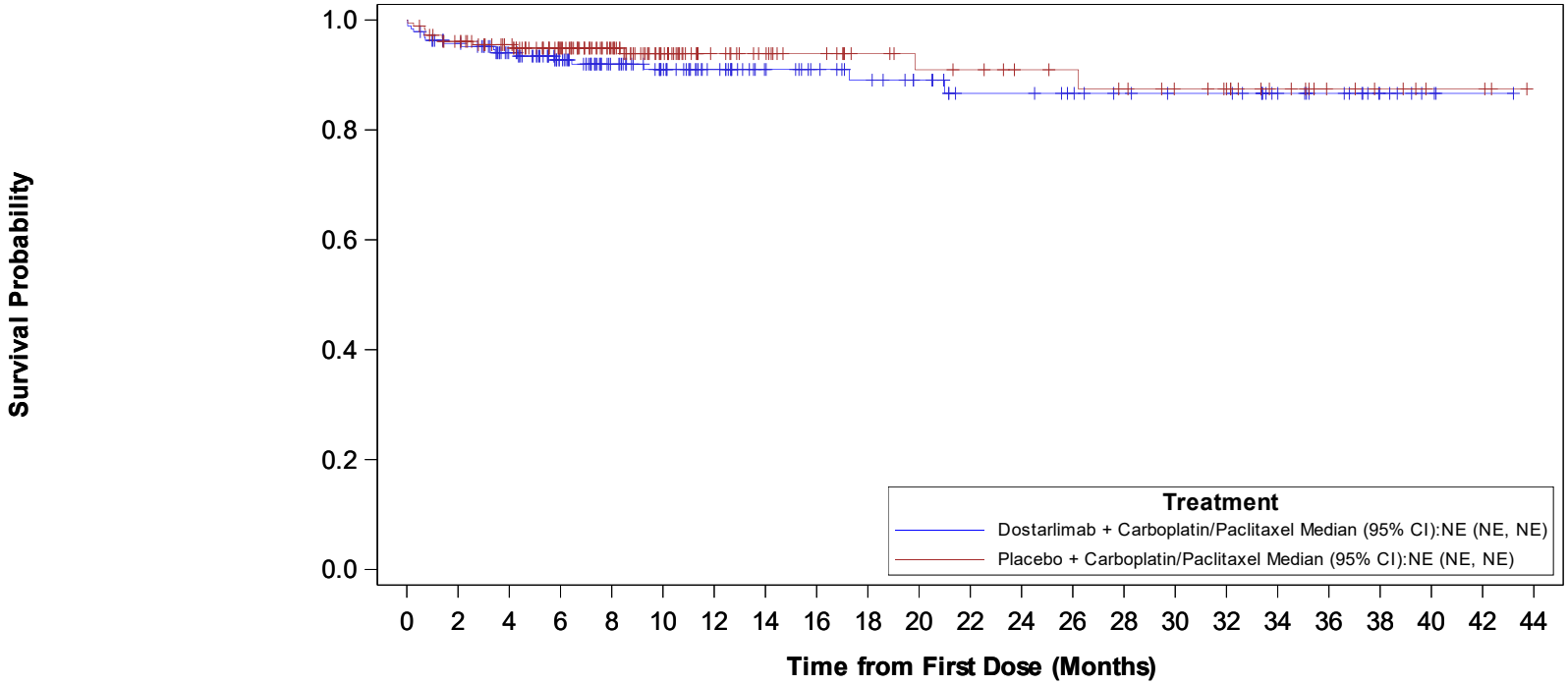
System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypokalaemia



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

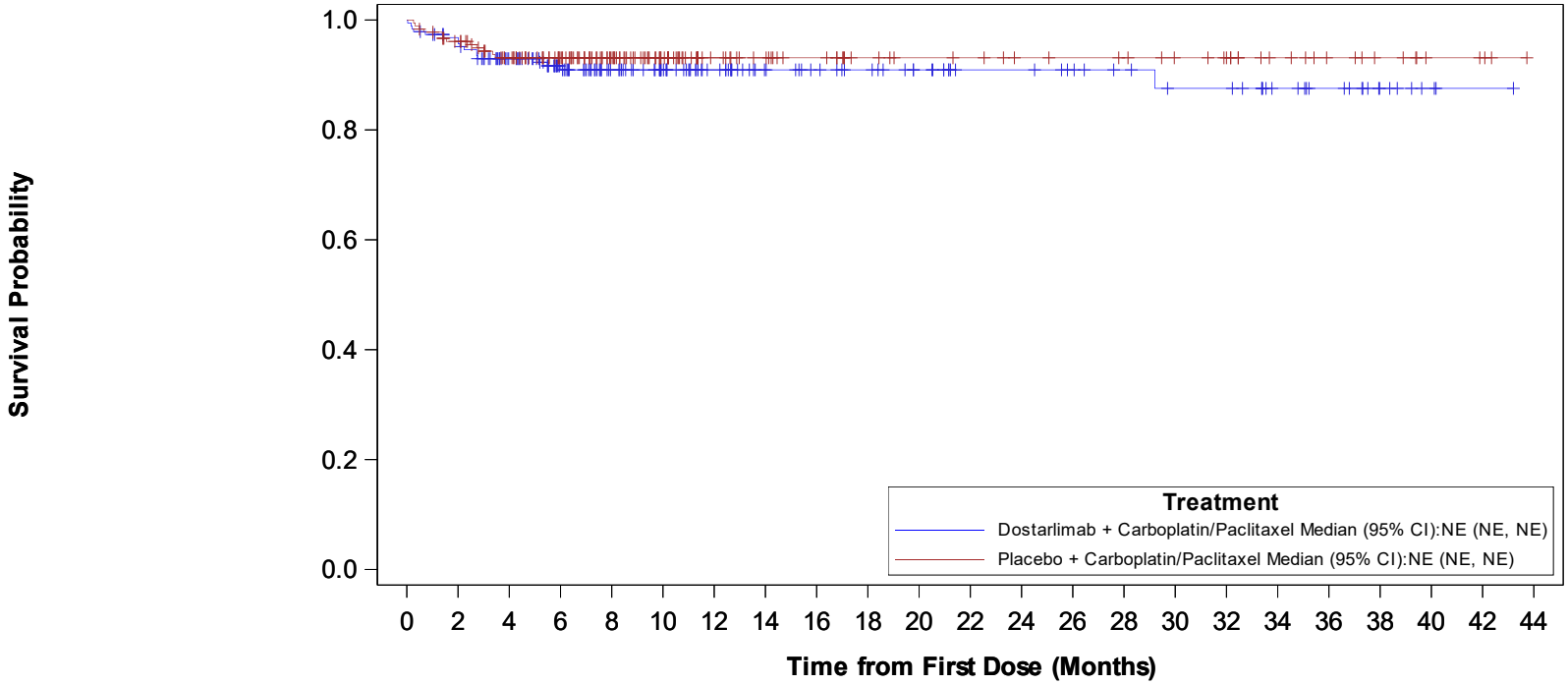
System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hyperglycaemia



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

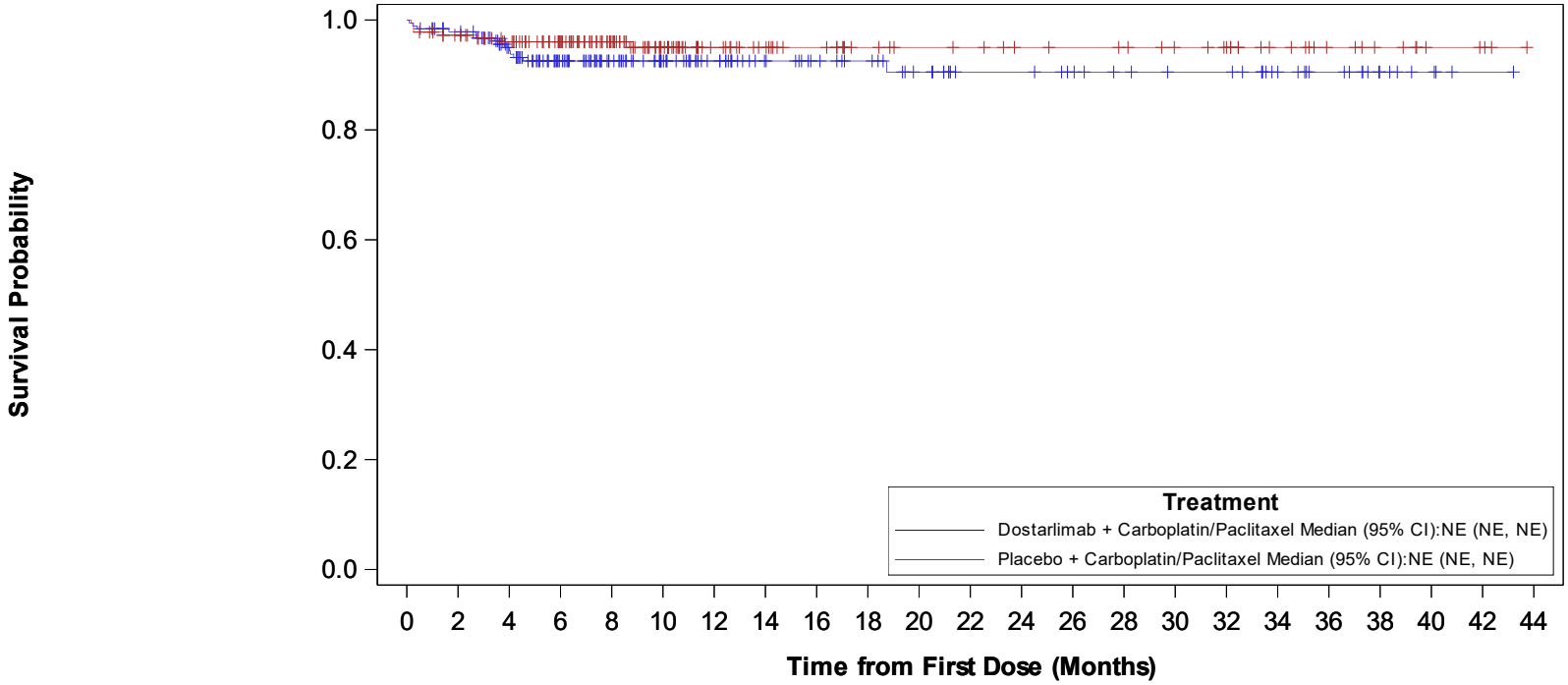
System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hyponatraemia



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

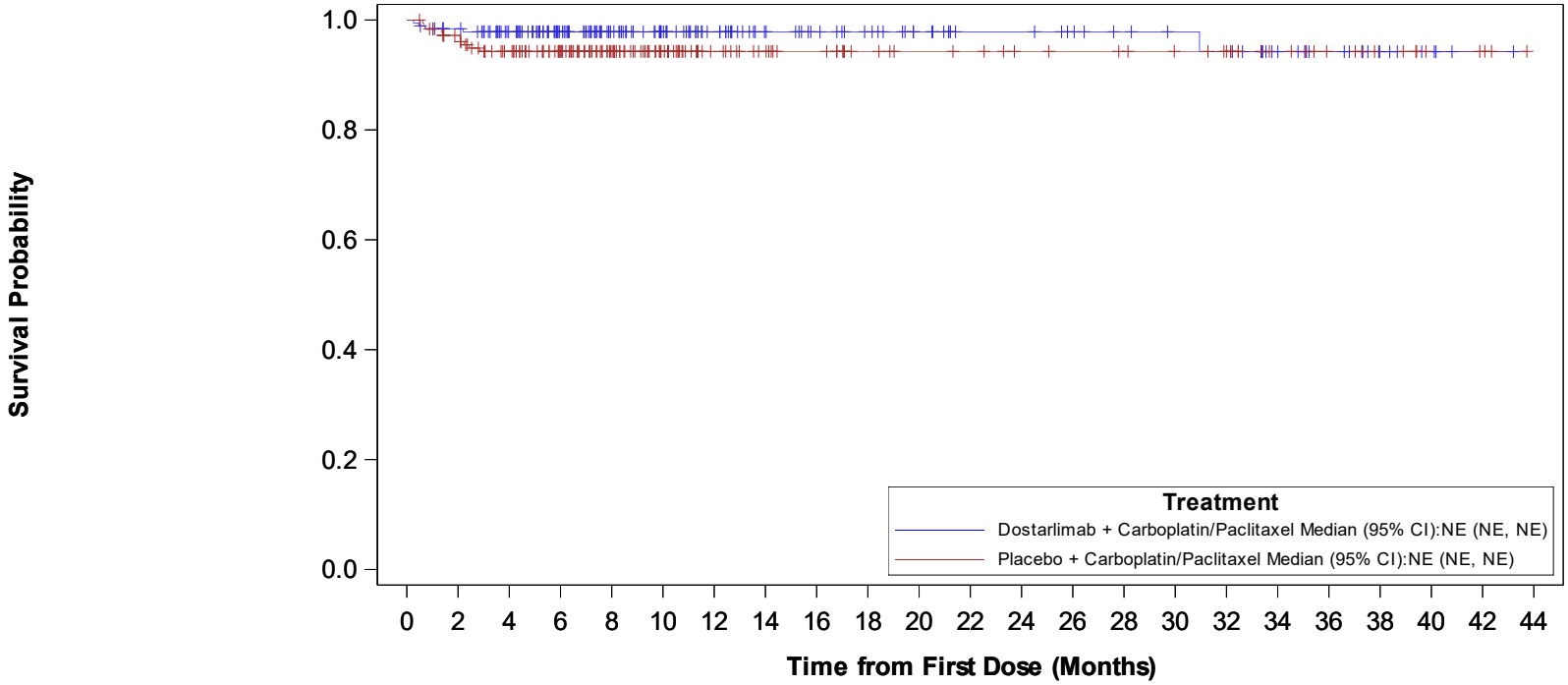
System Organ Class: Metabolism and nutrition disorders
Preferred Term: Dehydration



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

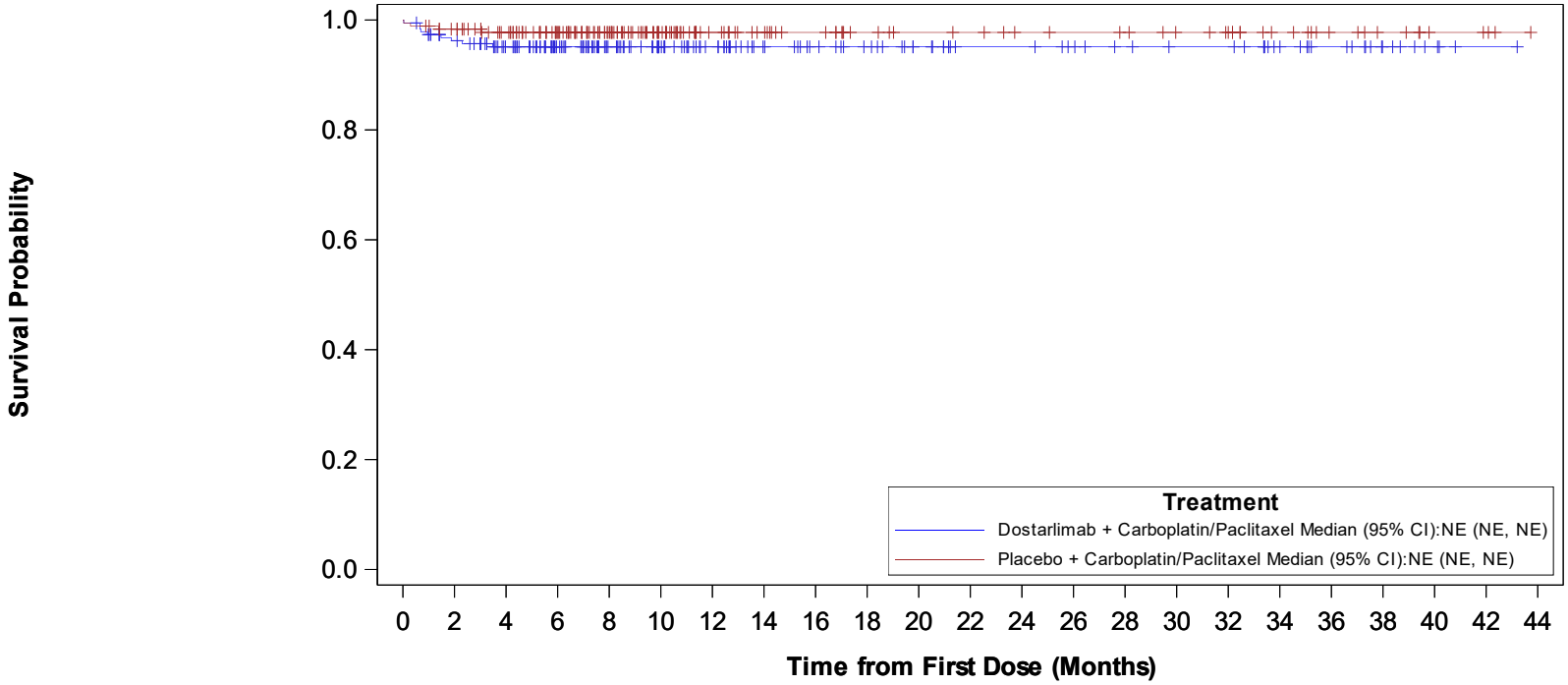
System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypophosphataemia



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypoalbuminaemia



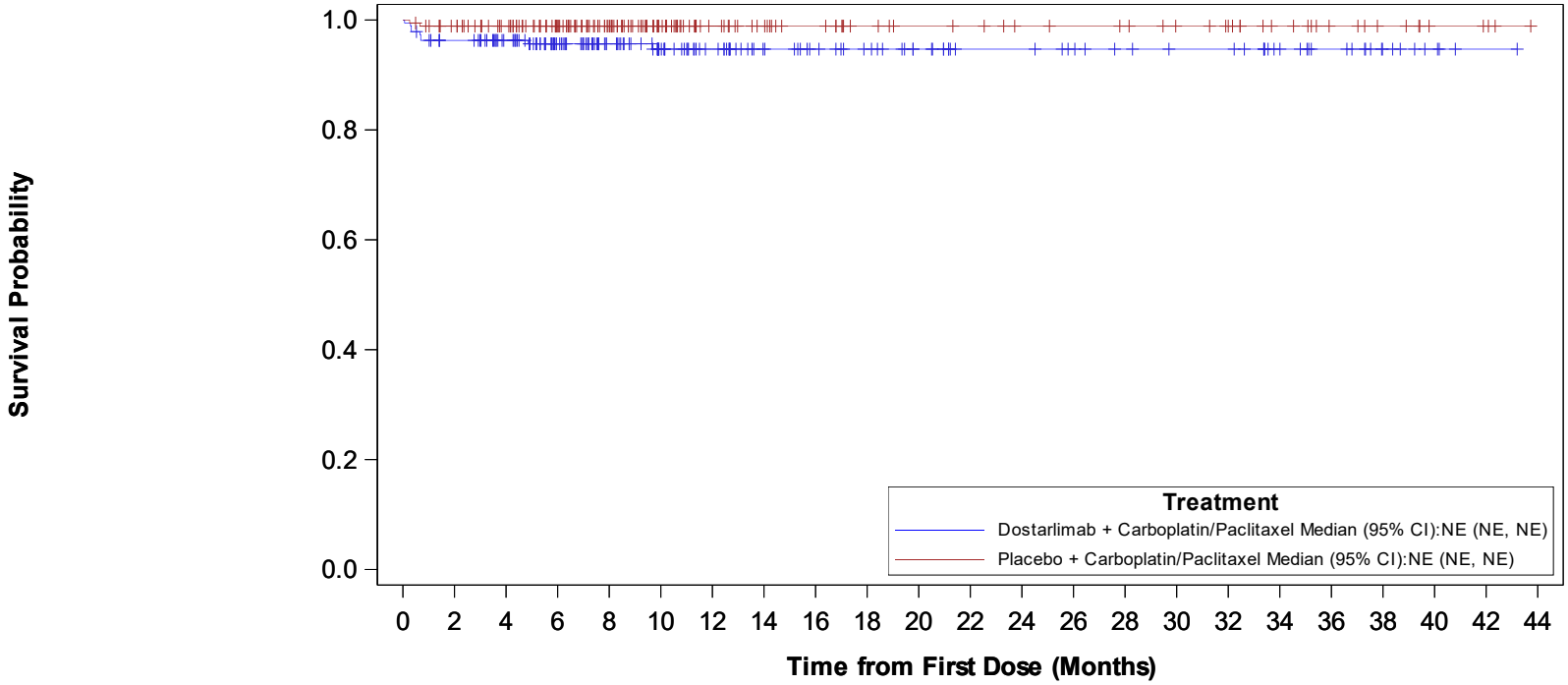
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	175(7)	159(9)	133(9)	109(9)	91(9)	76(9)	61(9)	55(9)	50(9)	43(9)	35(9)	35(9)	32(9)	29(9)	27(9)	27(9)	20(9)	15(9)	8(9)	4(9)	1(9)	0(9)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	173(3)	159(4)	135(4)	106(4)	80(4)	58(4)	50(4)	44(4)	37(4)	34(4)	33(4)	30(4)	29(4)	28(4)	25(4)	23(4)	16(4)	11(4)	8(4)	4(4)	3(4)	0(4)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypocalcaemia



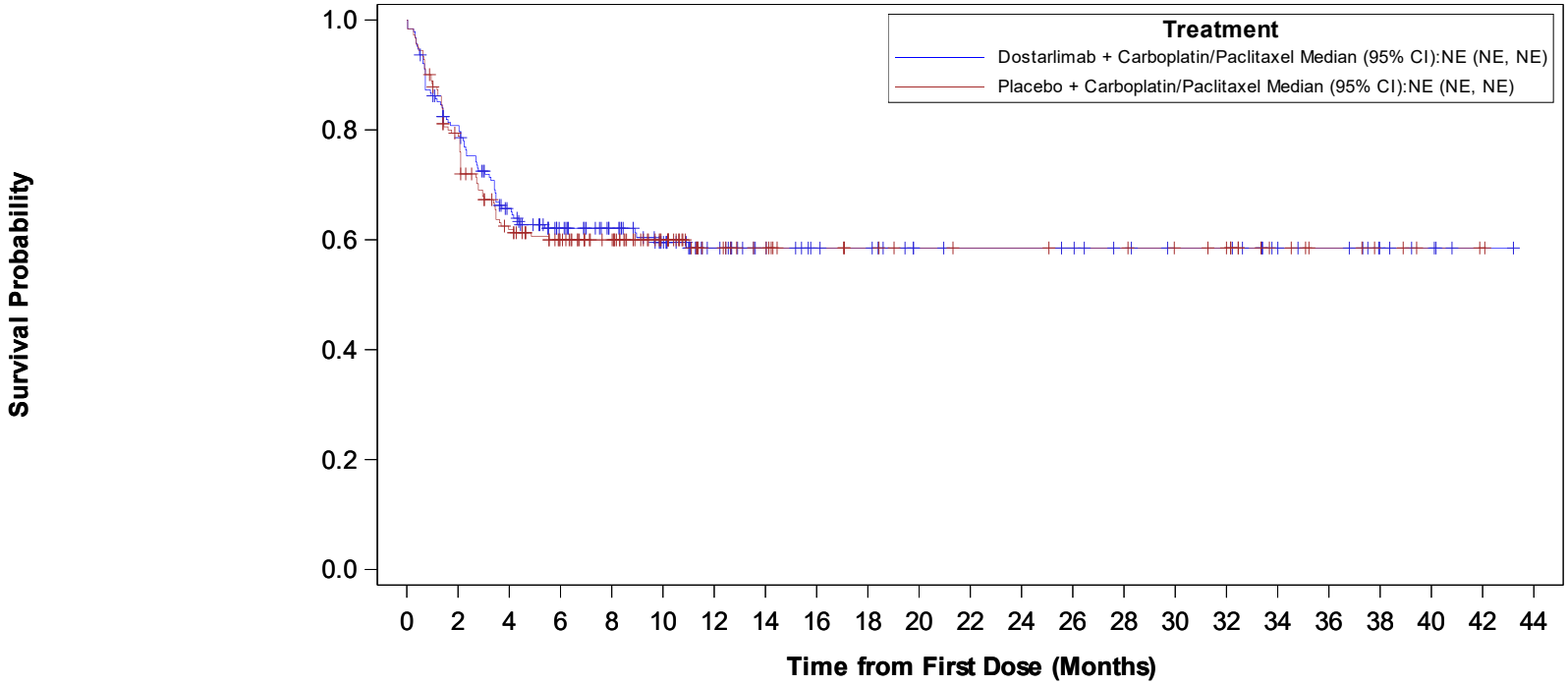
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	176(7)	162(7)	134(8)	109(8)	90(9)	75(9)	61(9)	55(9)	50(9)	43(9)	35(9)	35(9)	32(9)	29(9)	27(9)	27(9)	20(9)	15(9)	8(9)	4(9)	1(9)	0(9)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	172(2)	159(2)	133(2)	105(2)	79(2)	58(2)	50(2)	44(2)	37(2)	34(2)	33(2)	30(2)	29(2)	28(2)	25(2)	23(2)	16(2)	11(2)	8(2)	4(2)	3(2)	0(2)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Blood and lymphatic system disorders
Preferred Term: Anaemia



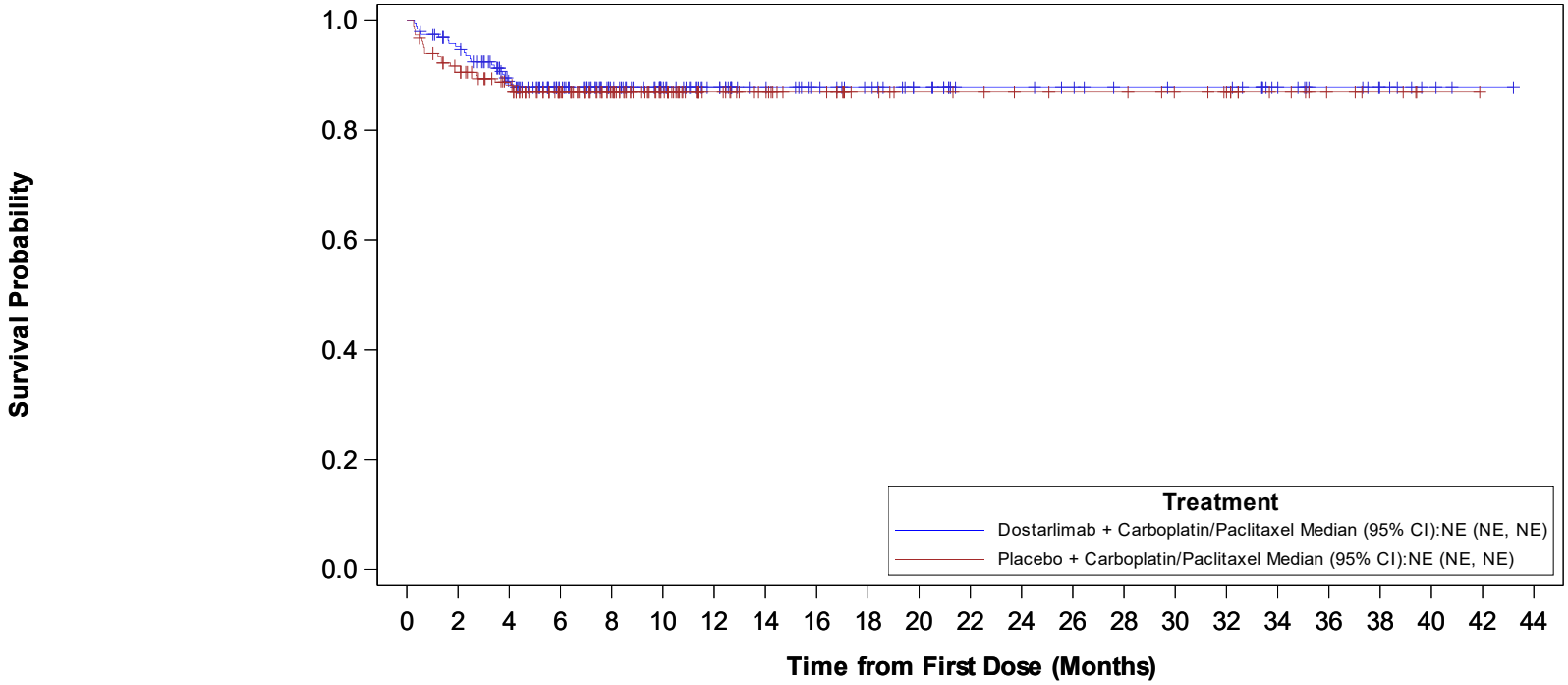
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	147(36)	112(63)	91(69)	78(69)	64(72)	48(73)	38(73)	33(73)	32(73)	26(73)	25(73)	25(73)	24(73)	21(73)	19(73)	19(73)	13(73)	11(73)	6(73)	4(73)	1(73)	0(73)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	139(37)	102(67)	86(70)	72(70)	52(70)	35(71)	30(71)	25(71)	23(71)	21(71)	20(71)	20(71)	19(71)	19(71)	17(71)	16(71)	9(71)	6(71)	4(71)	2(71)	1(71)	0(71)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Blood and lymphatic system disorders
Preferred Term: Neutropenia



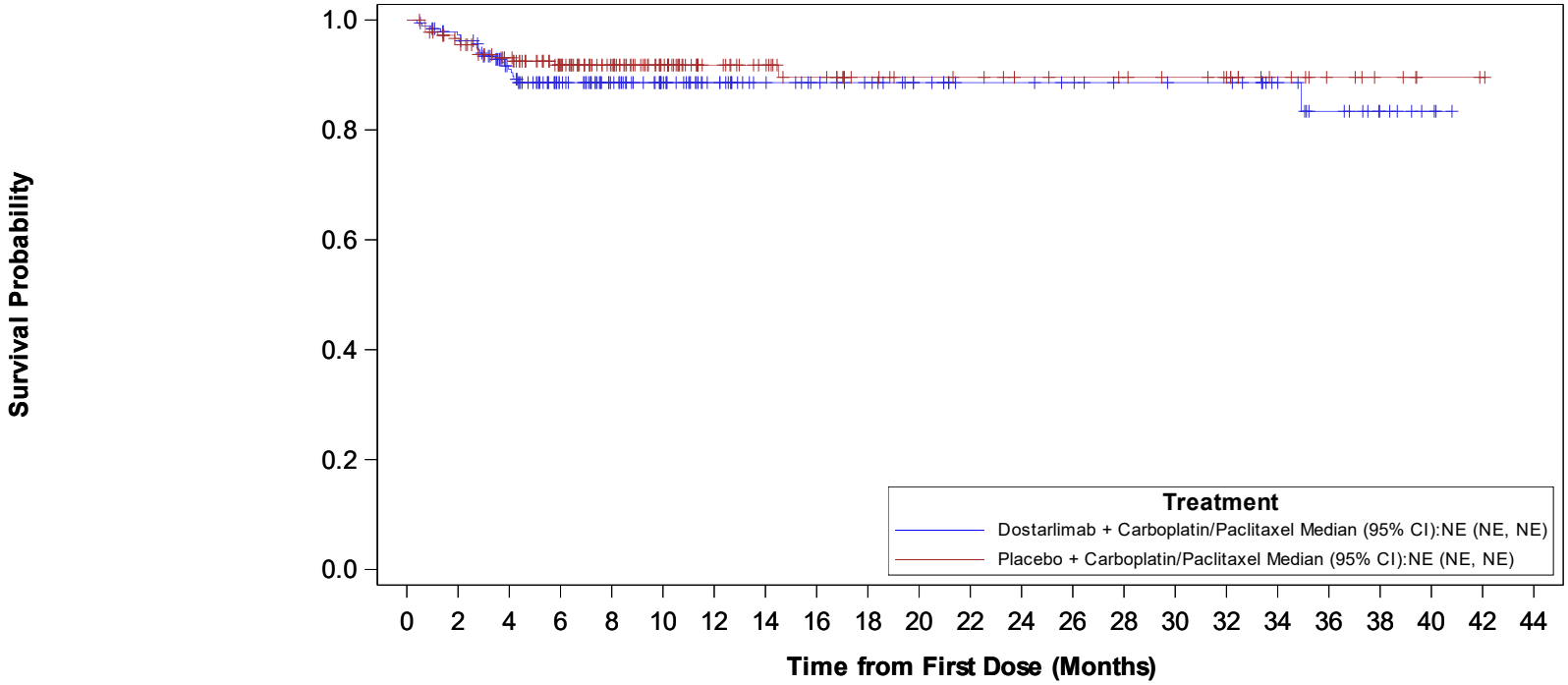
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	174(9)	147(20)	121(22)	98(22)	80(22)	66(22)	55(22)	49(22)	44(22)	37(22)	29(22)	29(22)	27(22)	24(22)	23(22)	23(22)	16(22)	11(22)	7(22)	3(22)	1(22)	0(22)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	161(15)	143(20)	115(23)	92(23)	69(23)	49(23)	41(23)	35(23)	28(23)	25(23)	24(23)	22(23)	21(23)	21(23)	18(23)	16(23)	10(23)	6(23)	4(23)	1(23)	0(23)	

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Blood and lymphatic system disorders
Preferred Term: Thrombocytopenia



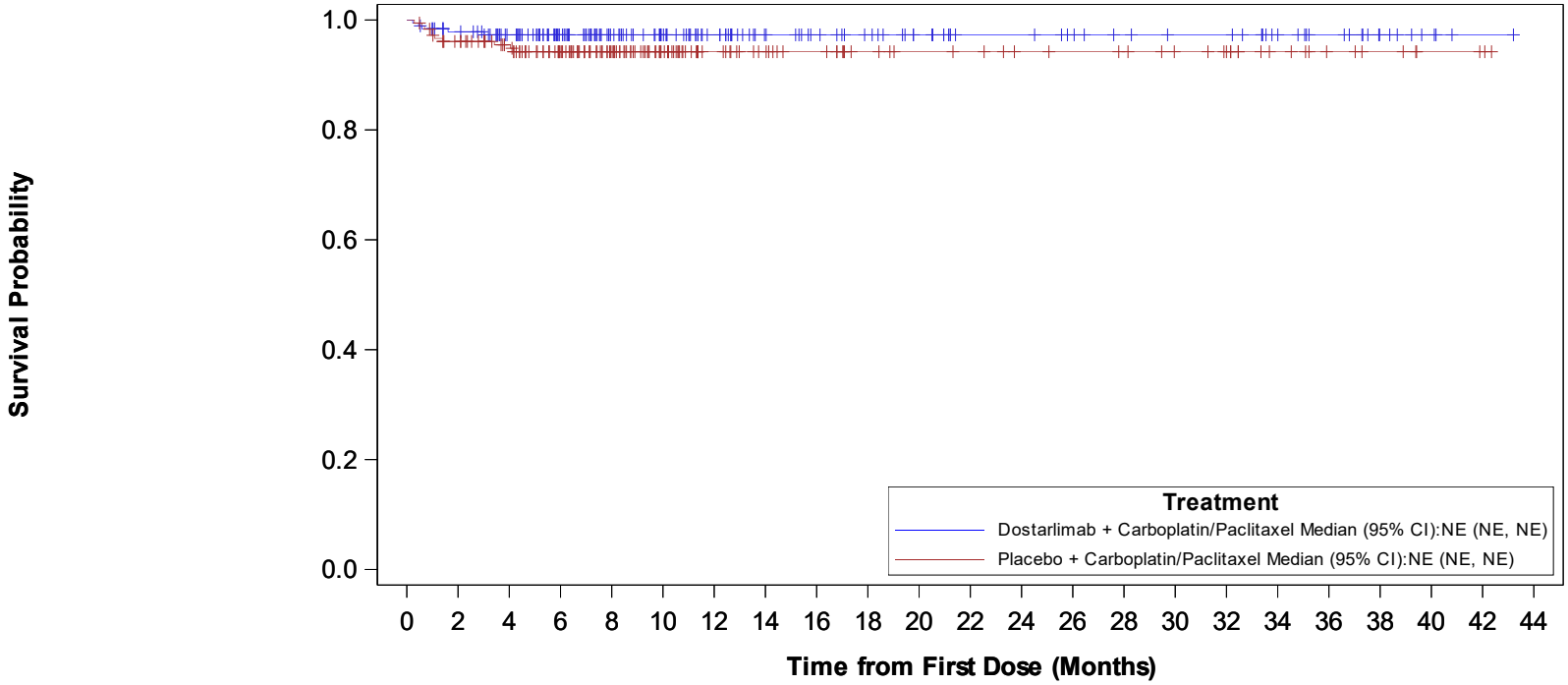
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	177(5)	150(16)	122(20)	101(20)	82(20)	66(20)	54(20)	49(20)	45(20)	38(20)	32(20)	32(20)	30(20)	27(20)	26(20)	26(20)	19(20)	13(21)	7(21)	3(21)	0(21)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	168(6)	151(12)	125(14)	100(14)	75(14)	54(14)	46(14)	39(15)	32(15)	29(15)	28(15)	25(15)	24(15)	23(15)	21(15)	19(15)	12(15)	8(15)	5(15)	2(15)	1(15)	0(15)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Blood and lymphatic system disorders
Preferred Term: Leukopenia



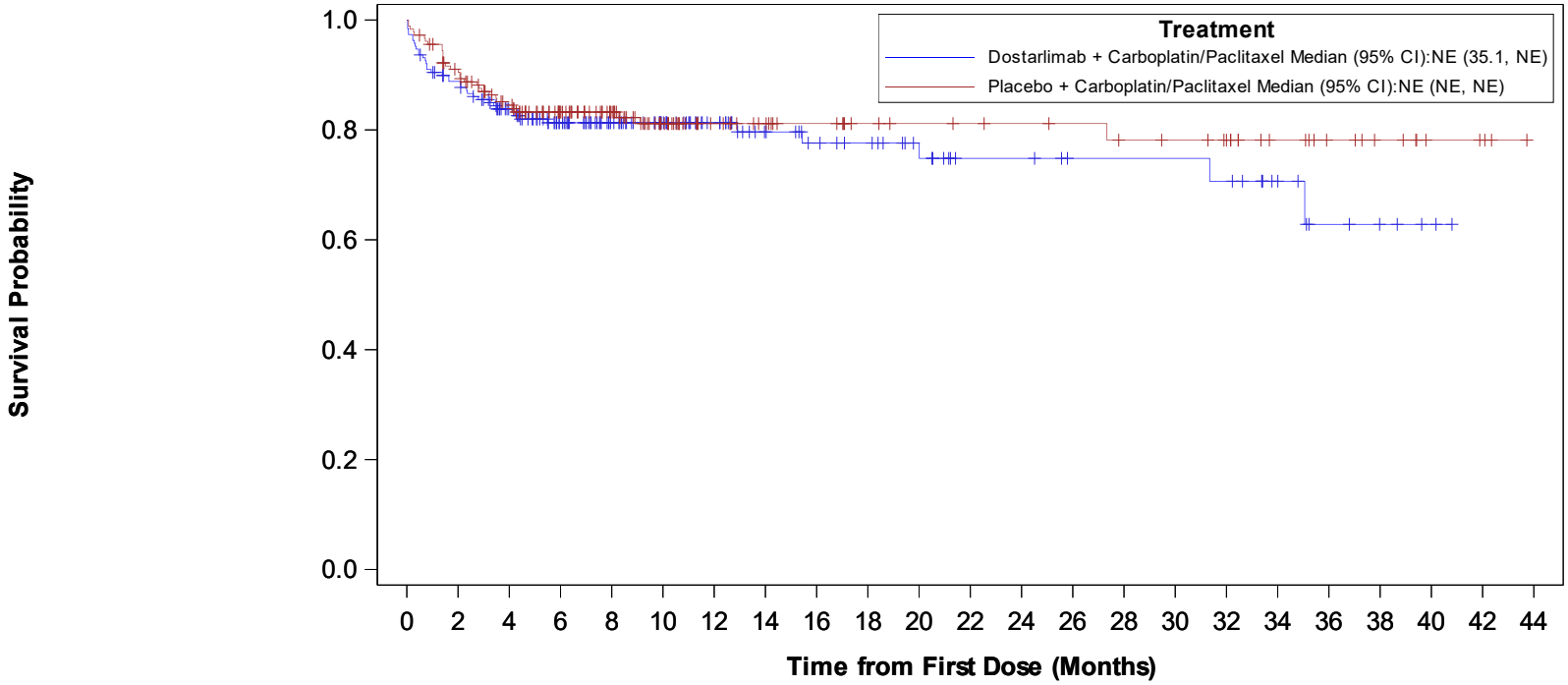
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	178(4)	162(5)	135(5)	110(5)	92(5)	76(5)	61(5)	55(5)	50(5)	43(5)	35(5)	35(5)	32(5)	29(5)	27(5)	27(5)	20(5)	15(5)	8(5)	4(5)	1(5)	0(5)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	167(7)	153(8)	127(10)	100(10)	74(10)	53(10)	45(10)	40(10)	33(10)	30(10)	29(10)	26(10)	25(10)	24(10)	21(10)	19(10)	12(10)	8(10)	6(10)	3(10)	2(10)	0(10)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders
Preferred Term: Dyspnoea



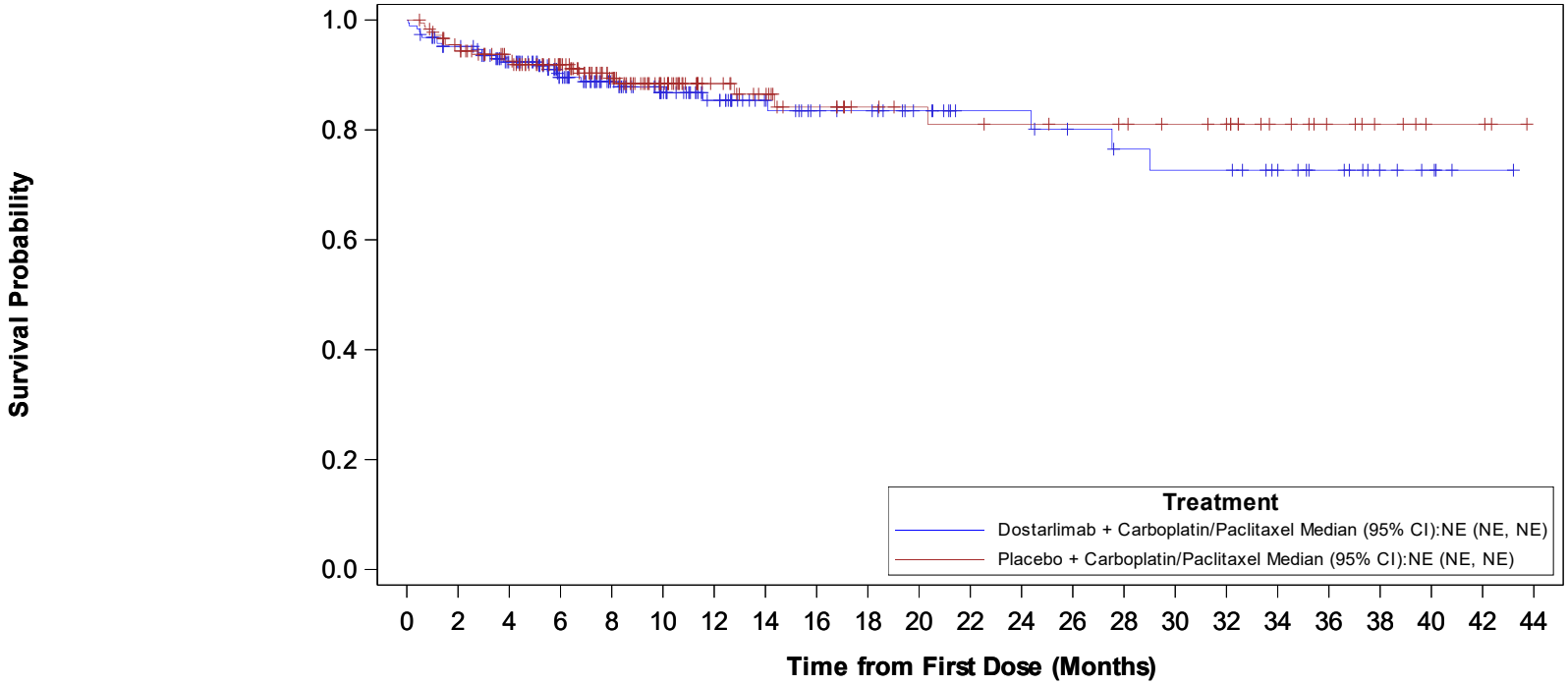
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	162(21)	138(30)	113(34)	91(34)	73(34)	57(34)	43(35)	37(36)	34(36)	28(36)	21(37)	21(37)	18(37)	18(37)	18(37)	17(38)	11(38)	6(39)	4(39)	2(39)	0(39)	
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	158(16)	136(27)	109(29)	88(29)	64(31)	48(31)	42(31)	37(31)	32(31)	30(31)	29(31)	28(31)	27(31)	25(32)	24(32)	22(32)	15(32)	11(32)	8(32)	4(32)	3(32)	0(32)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders
Preferred Term: Cough

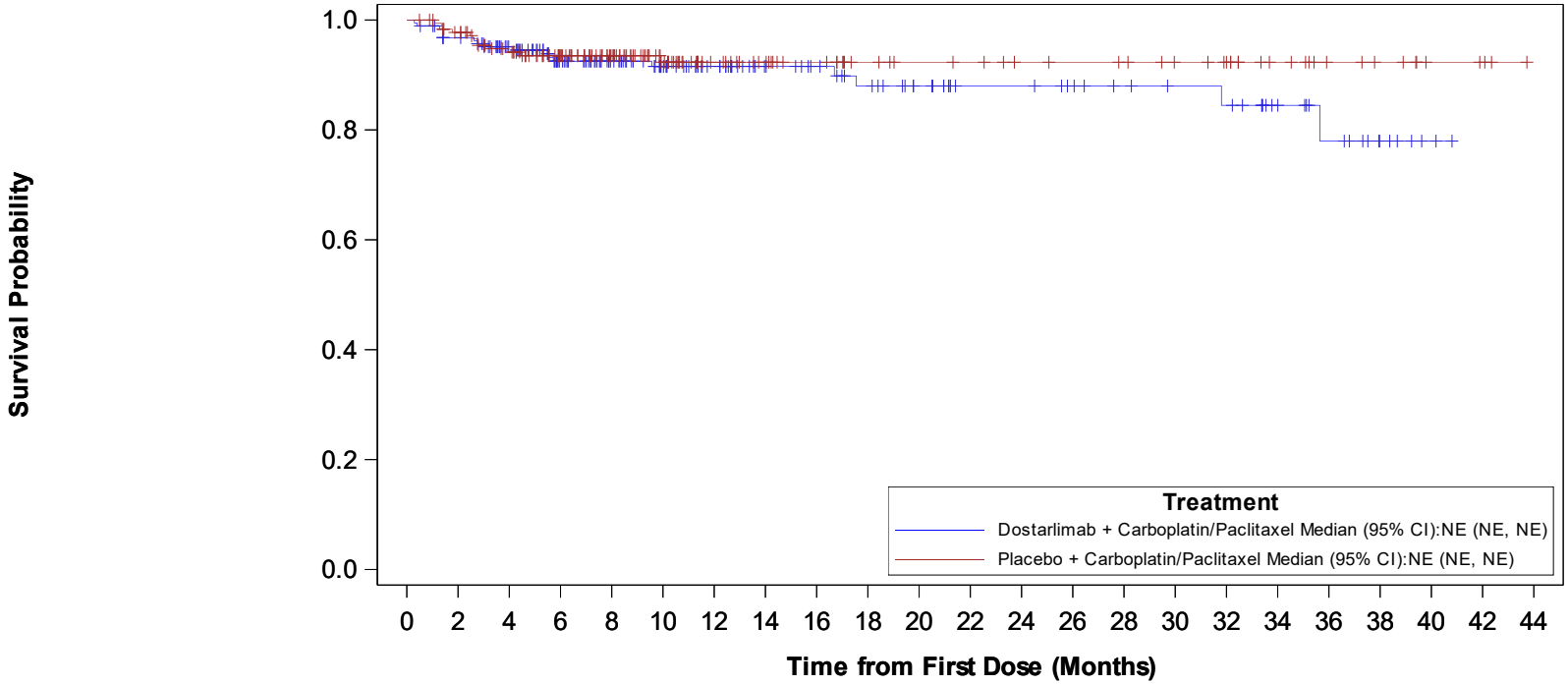


Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	173(9)	152(14)	120(18)	96(19)	77(21)	60(22)	46(22)	39(23)	37(23)	31(23)	25(23)	25(23)	22(24)	20(25)	19(26)	19(26)	15(26)	11(26)	6(26)	4(26)	1(26)	0(26)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	166(8)	148(13)	126(14)	96(17)	70(18)	49(18)	41(19)	34(20)	29(20)	27(20)	26(21)	25(21)	24(21)	23(21)	21(21)	20(21)	13(21)	9(21)	6(21)	3(21)	3(21)	0(21)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Respiratory, thoracic and mediastinal disorders
Preferred Term: Pulmonary embolism



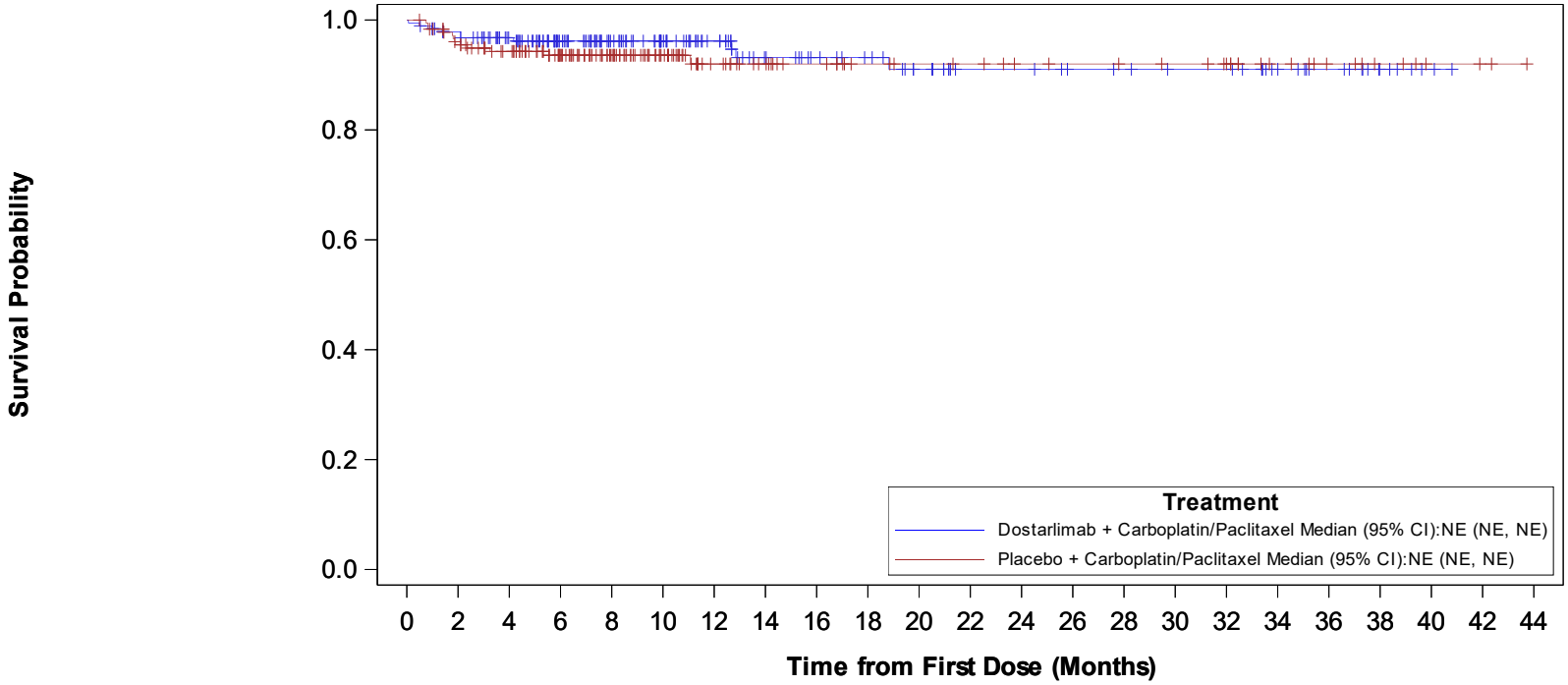
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	177(6)	158(9)	128(13)	107(13)	88(14)	74(14)	59(14)	54(14)	48(16)	41(16)	33(16)	33(16)	30(16)	27(16)	25(16)	24(17)	17(17)	12(18)	6(18)	2(18)	0(18)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	170(4)	152(10)	127(11)	102(11)	77(12)	56(12)	49(12)	43(12)	36(12)	33(12)	32(12)	29(12)	28(12)	27(12)	24(12)	22(12)	15(12)	10(12)	8(12)	4(12)	3(12)	0(12)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders
Preferred Term: Dyspnoea exertional

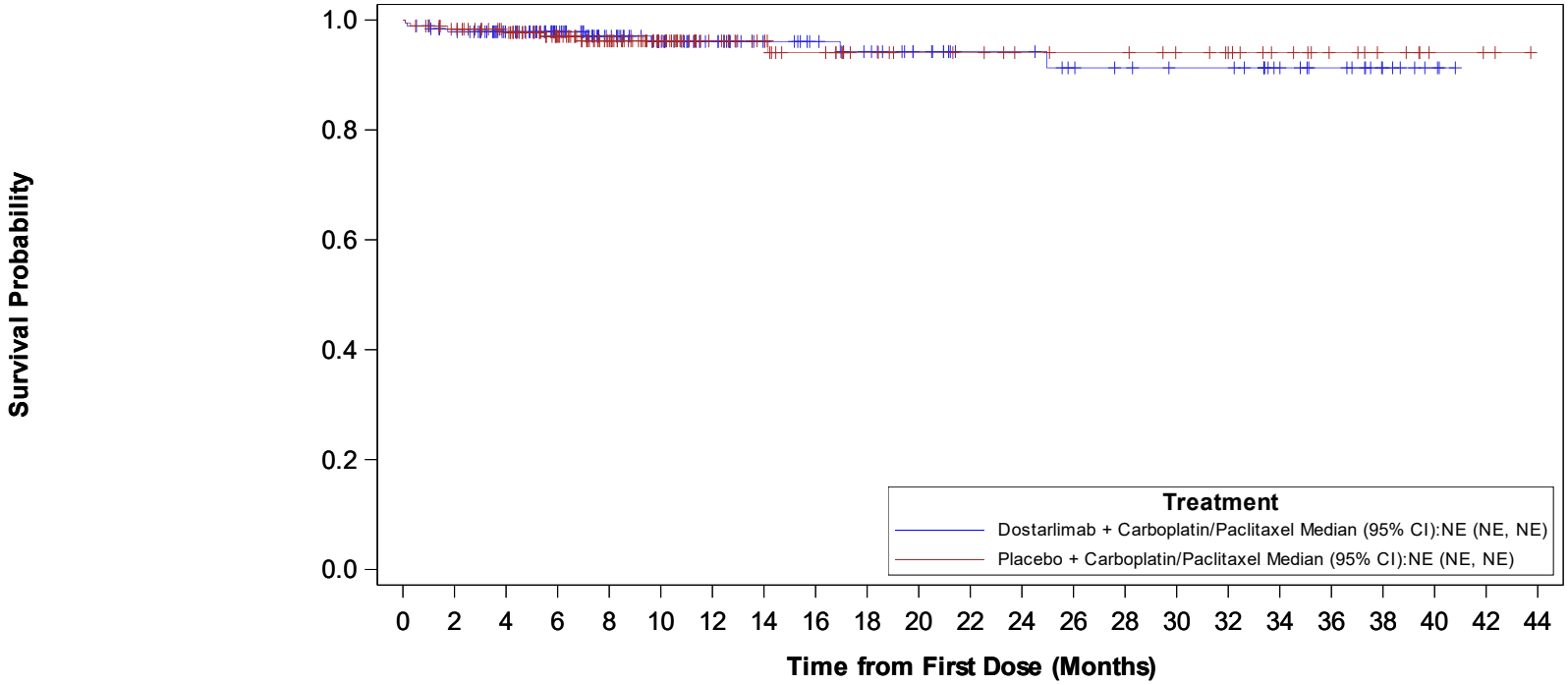


Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	178(4)	160(6)	131(7)	107(7)	88(7)	72(7)	56(9)	50(9)	46(9)	39(10)	31(10)	31(10)	28(10)	27(10)	25(10)	25(10)	18(10)	13(10)	6(10)	2(10)	0(10)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	166(8)	152(10)	125(11)	98(11)	73(11)	51(12)	43(12)	37(12)	31(12)	29(12)	28(12)	25(12)	24(12)	23(12)	22(12)	20(12)	13(12)	9(12)	6(12)	3(12)	2(12)	0(12)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Respiratory, thoracic and mediastinal disorders
Preferred Term: Oropharyngeal pain



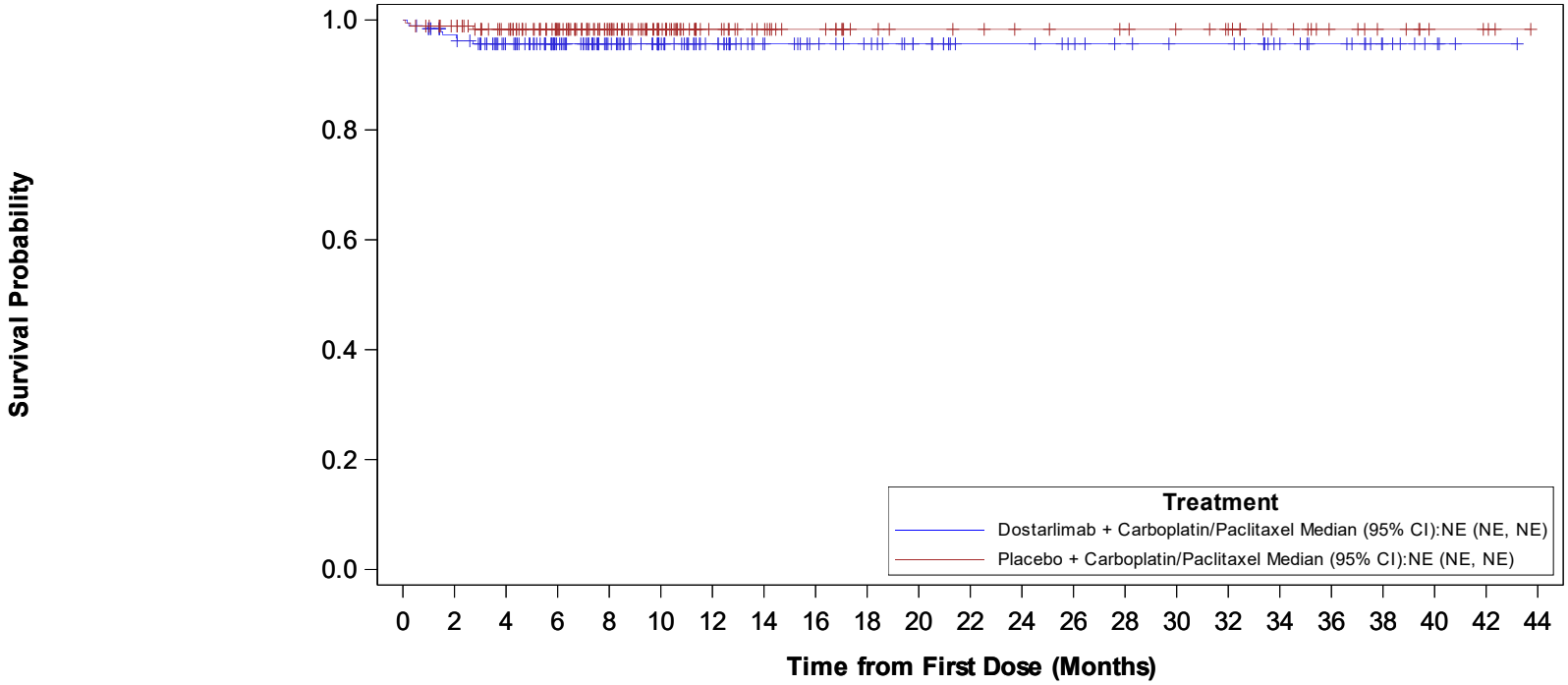
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	178(4)	161(4)	134(4)	109(5)	89(6)	73(6)	59(6)	53(6)	48(7)	41(7)	33(7)	33(7)	29(8)	27(8)	25(8)	25(8)	18(8)	14(8)	7(8)	3(8)	0(8)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	171(3)	158(4)	131(5)	102(6)	77(6)	55(6)	47(6)	40(7)	33(7)	30(7)	29(7)	26(7)	25(7)	25(7)	22(7)	20(7)	14(7)	10(7)	7(7)	3(7)	2(7)	0(7)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders
Preferred Term: Epistaxis



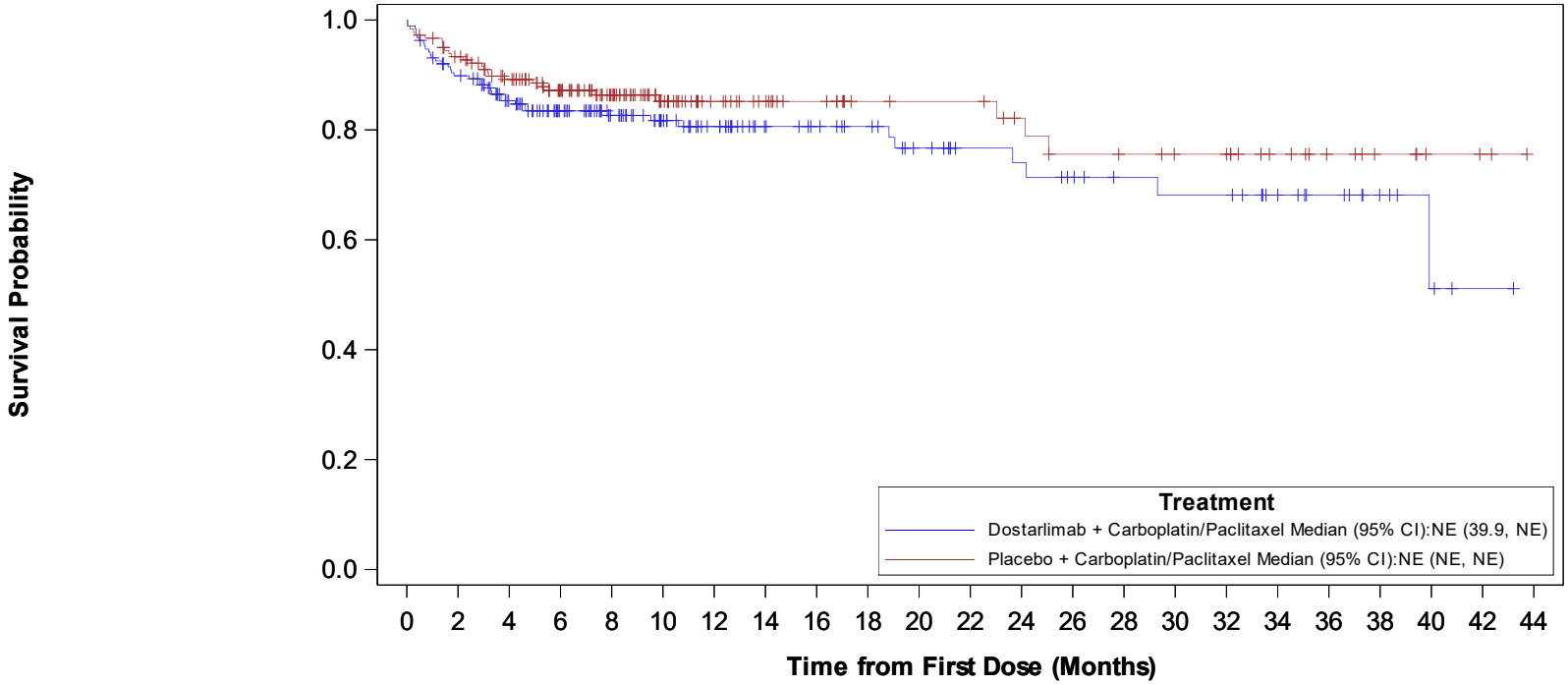
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	177(5)	159(8)	134(8)	109(8)	90(8)	74(8)	59(8)	53(8)	49(8)	42(8)	34(8)	34(8)	31(8)	28(8)	26(8)	26(8)	19(8)	15(8)	8(8)	4(8)	1(8)	0(8)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	172(2)	158(3)	132(3)	103(3)	77(3)	55(3)	47(3)	41(3)	34(3)	32(3)	31(3)	29(3)	28(3)	27(3)	25(3)	23(3)	16(3)	11(3)	8(3)	4(3)	3(3)	0(3)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Urinary tract infection



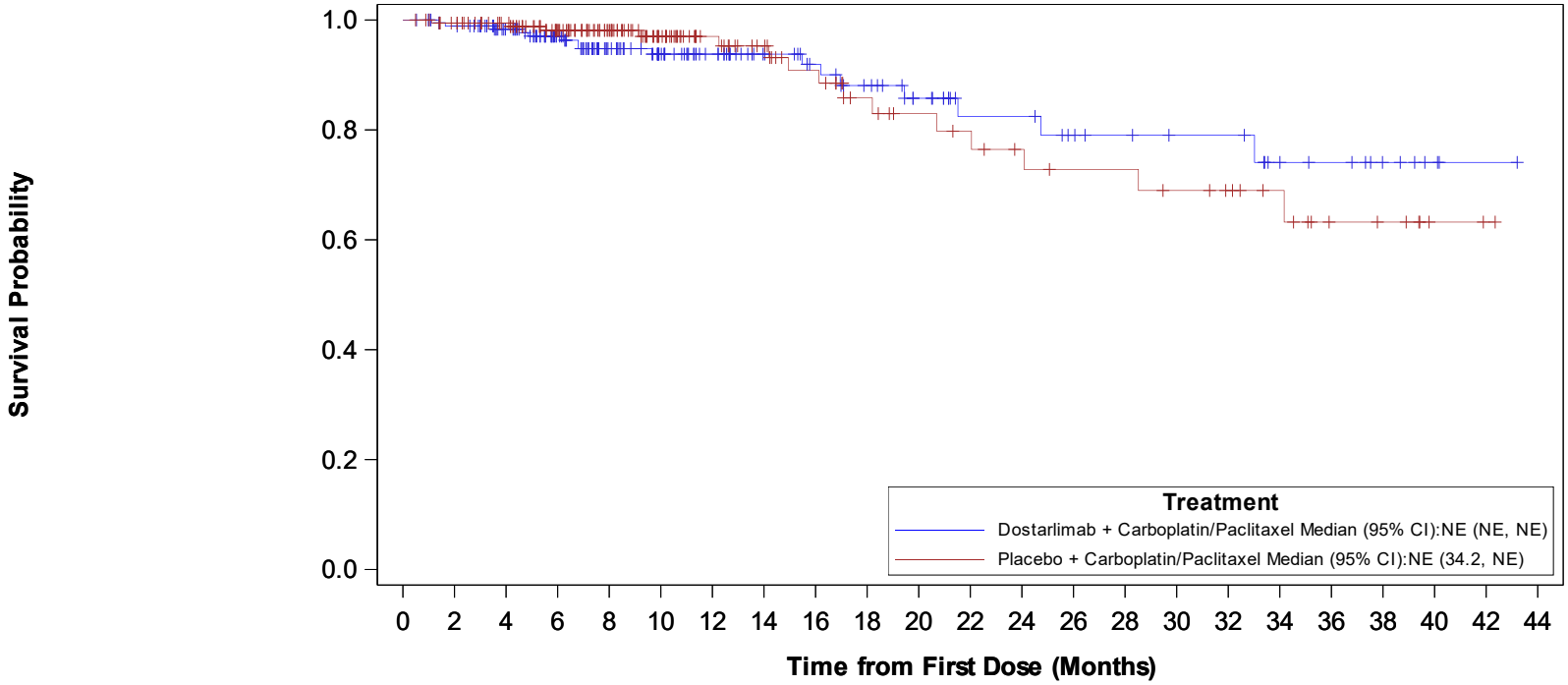
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	165(19)	142(27)	118(30)	97(31)	79(32)	66(33)	51(33)	47(33)	43(33)	36(35)	29(35)	28(36)	25(37)	22(37)	21(38)	21(38)	15(38)	11(38)	6(38)	3(39)	1(39)	0(39)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	164(12)	146(19)	120(22)	96(23)	69(24)	50(24)	43(24)	37(24)	30(24)	29(24)	29(24)	25(25)	22(27)	21(27)	19(27)	19(27)	13(27)	9(27)	6(27)	3(27)	2(27)	0(27)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: COVID-19



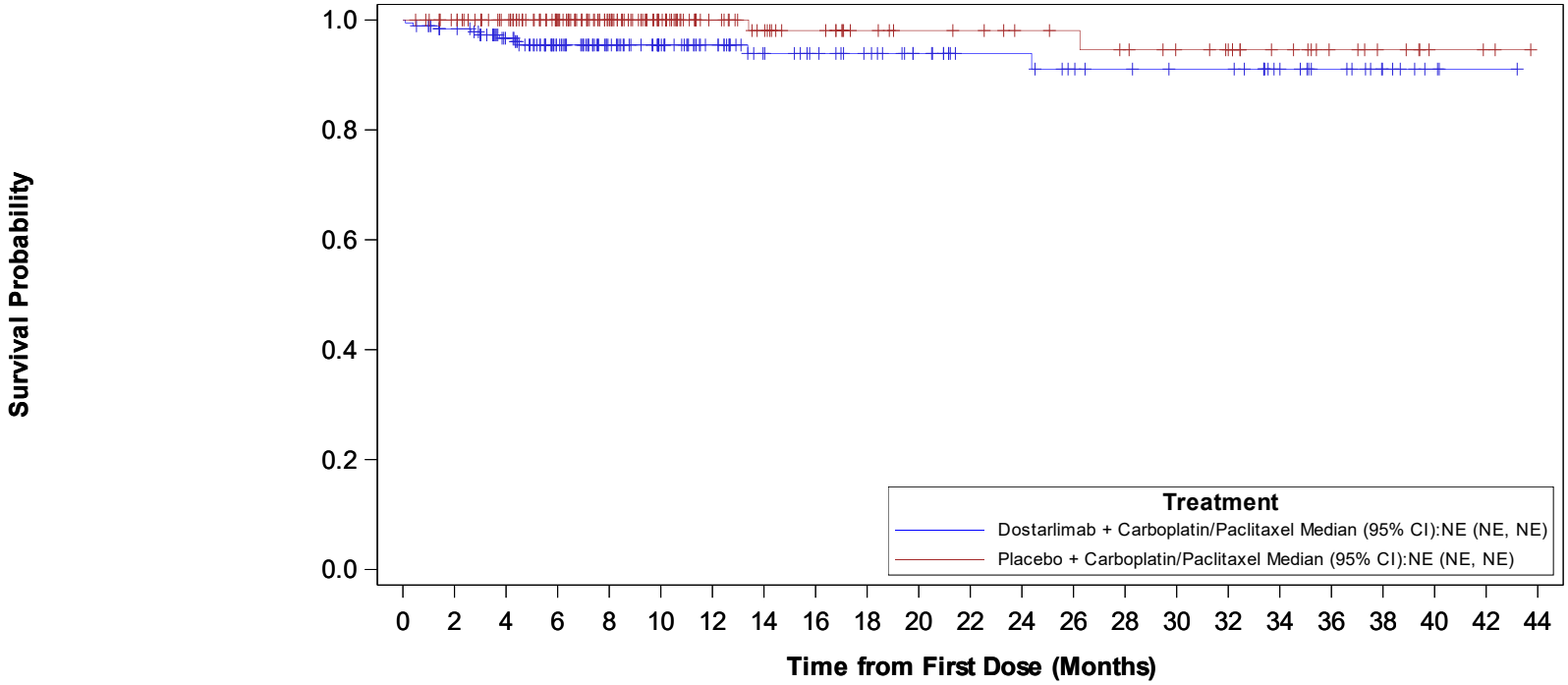
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	180(2)	162(3)	133(5)	104(8)	85(9)	70(9)	55(9)	48(10)	42(12)	34(13)	25(14)	25(14)	21(15)	19(15)	17(15)	17(15)	12(16)	10(16)	6(16)	3(16)	1(16)	0(16)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	173(1)	160(1)	132(3)	104(3)	77(4)	56(4)	47(5)	39(7)	30(9)	26(10)	24(11)	21(12)	19(13)	19(13)	17(14)	15(14)	12(14)	7(15)	6(15)	2(15)	1(15)	0(15)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Pneumonia



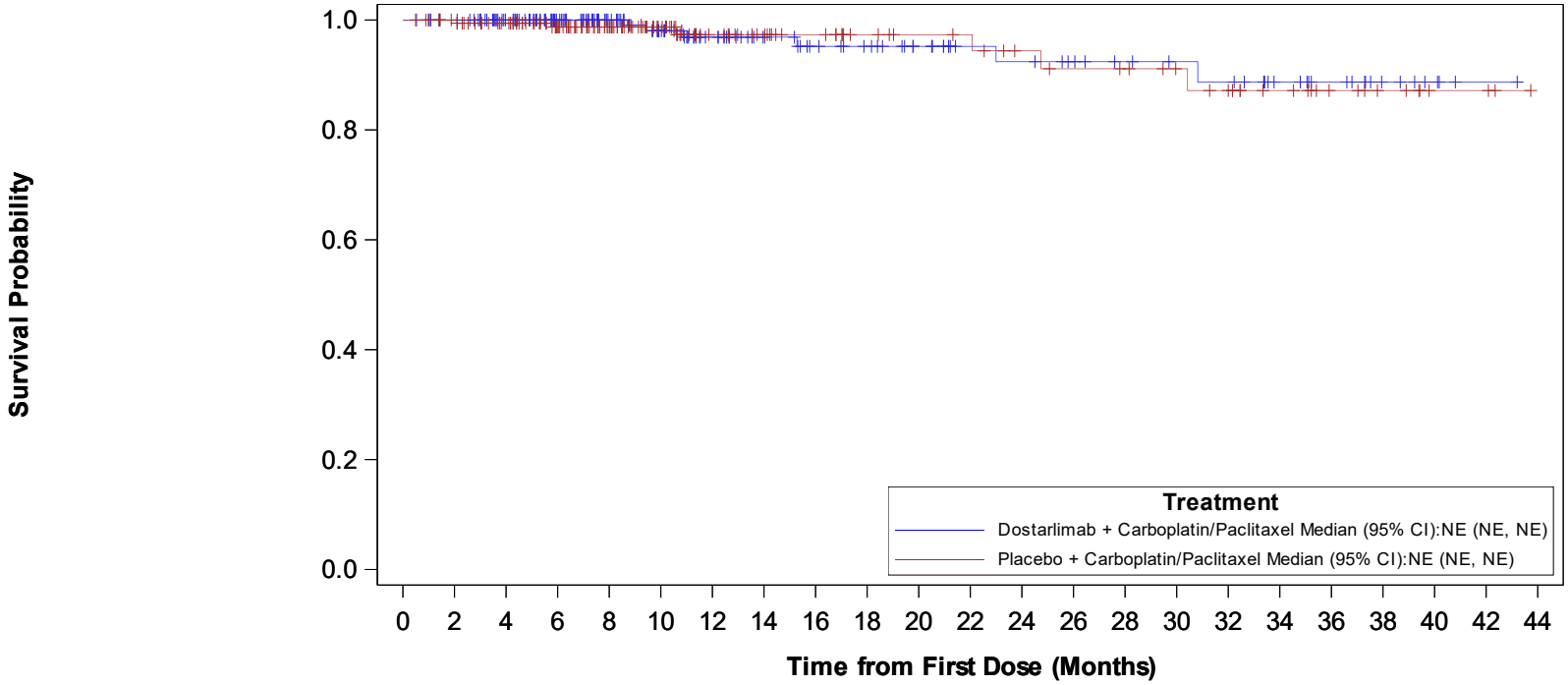
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	179(3)	160(6)	132(8)	108(8)	89(8)	73(8)	58(9)	53(9)	48(9)	41(9)	33(9)	33(9)	29(10)	27(10)	25(10)	25(10)	18(10)	13(10)	7(10)	3(10)	1(10)	0(10)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	174(0)	161(0)	135(0)	106(0)	80(0)	58(0)	49(1)	43(1)	36(1)	33(1)	32(1)	29(1)	28(1)	26(2)	23(2)	21(2)	15(2)	10(2)	7(2)	3(2)	2(2)	0(2)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Upper respiratory tract infection



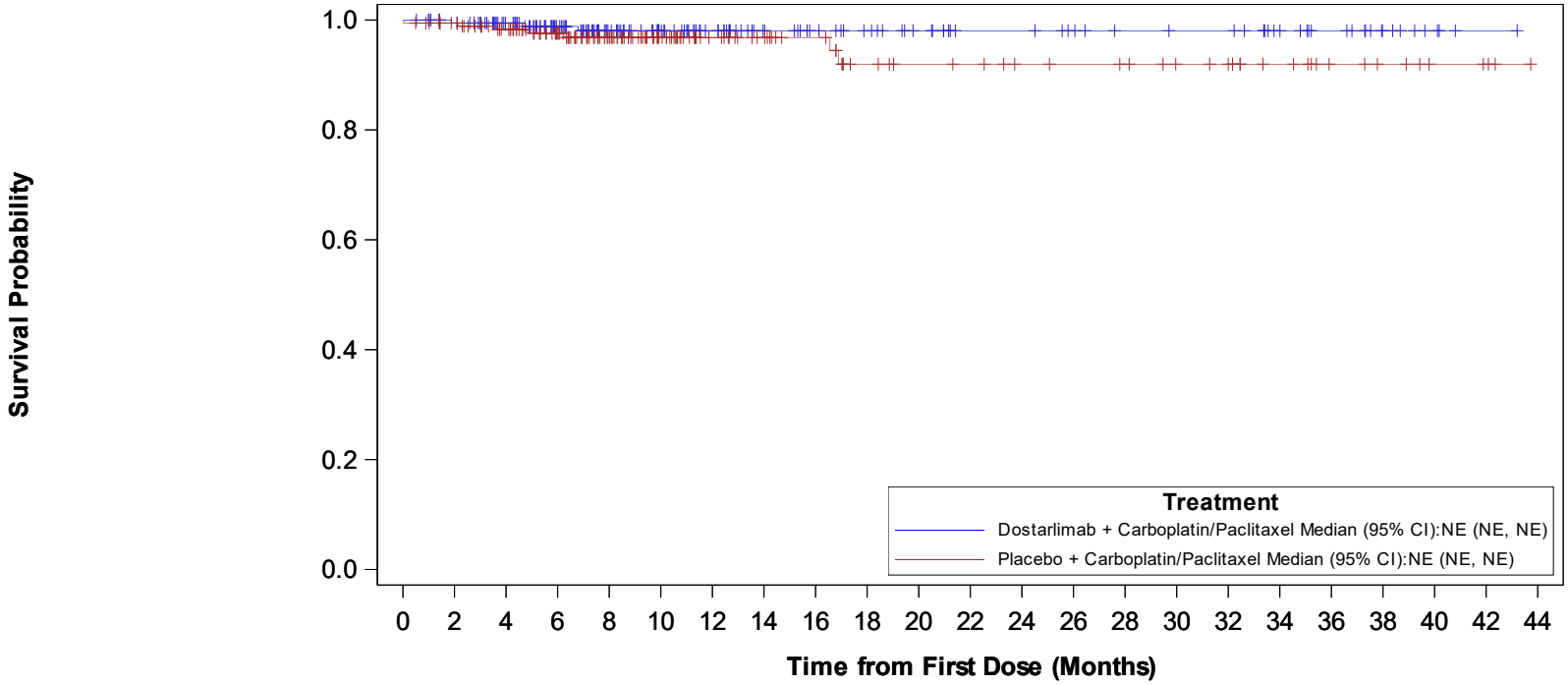
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	182(0)	165(0)	137(0)	111(0)	90(2)	73(3)	60(3)	53(4)	49(4)	42(4)	34(4)	33(5)	30(5)	27(5)	25(5)	24(6)	17(6)	13(6)	7(6)	4(6)	1(6)	0(6)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	174(0)	160(1)	134(2)	105(2)	80(2)	57(3)	50(3)	44(3)	37(3)	34(3)	33(3)	29(4)	27(5)	26(5)	23(5)	21(6)	15(6)	10(6)	7(6)	3(6)	3(6)	0(6)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Tooth infection



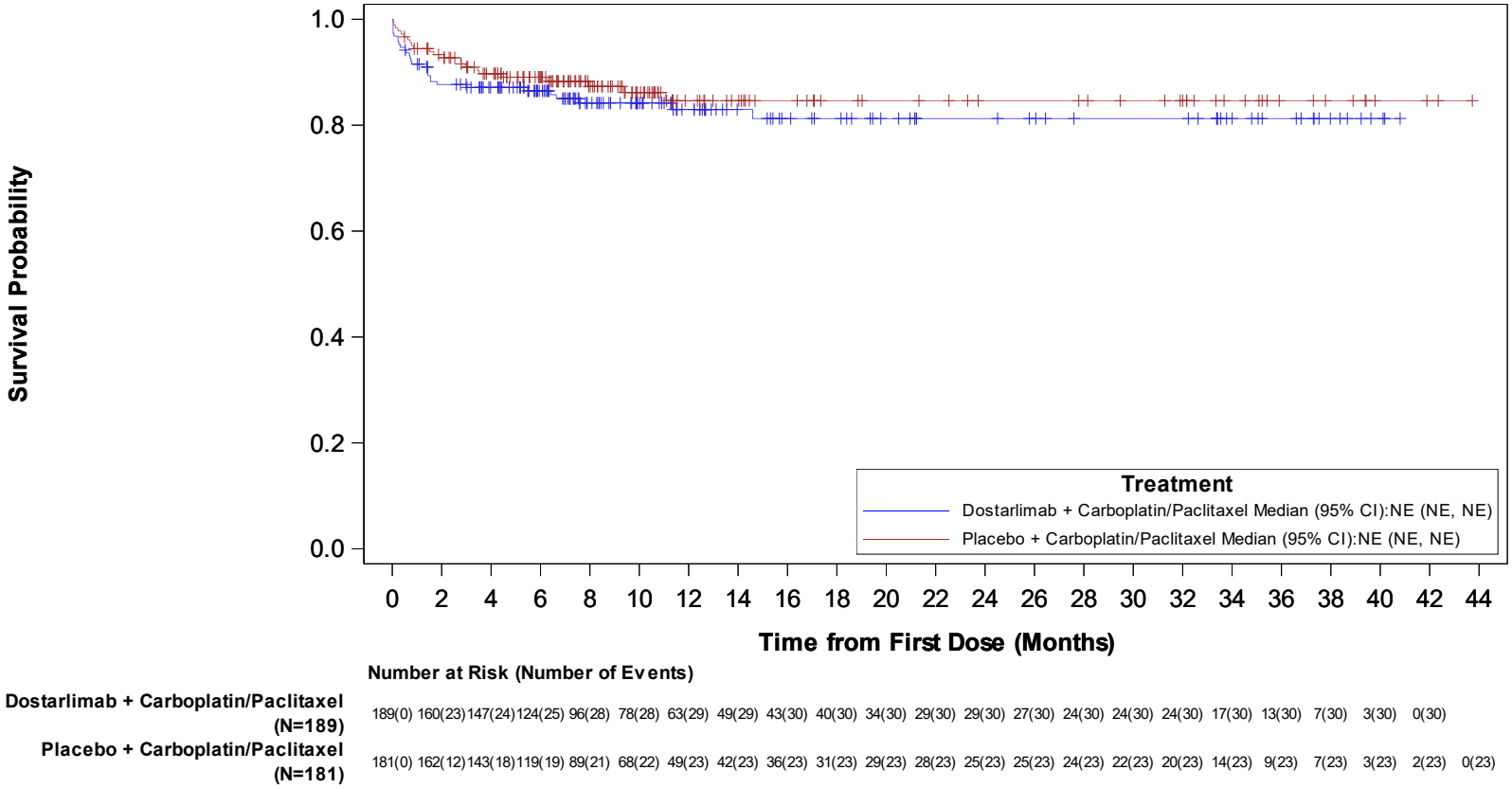
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	181(1)	164(1)	135(2)	108(3)	89(3)	74(3)	59(3)	53(3)	48(3)	42(3)	34(3)	34(3)	31(3)	28(3)	27(3)	27(3)	20(3)	15(3)	8(3)	4(3)	1(3)	0(3)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	173(1)	158(3)	131(4)	101(5)	76(5)	56(5)	48(5)	42(5)	33(7)	30(7)	29(7)	26(7)	25(7)	24(7)	21(7)	20(7)	14(7)	9(7)	7(7)	4(7)	3(7)	0(7)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

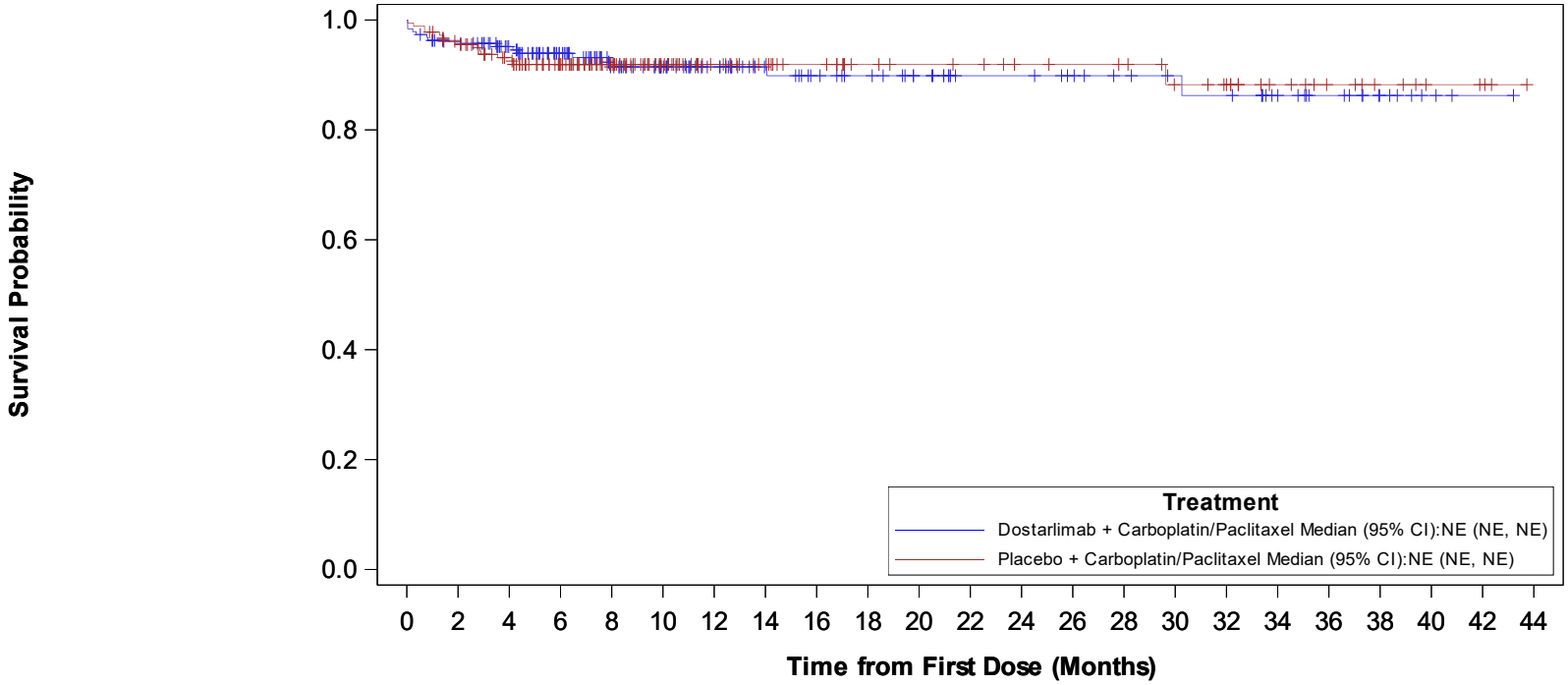
System Organ Class: Psychiatric disorders
Preferred Term: Insomnia



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Anxiety



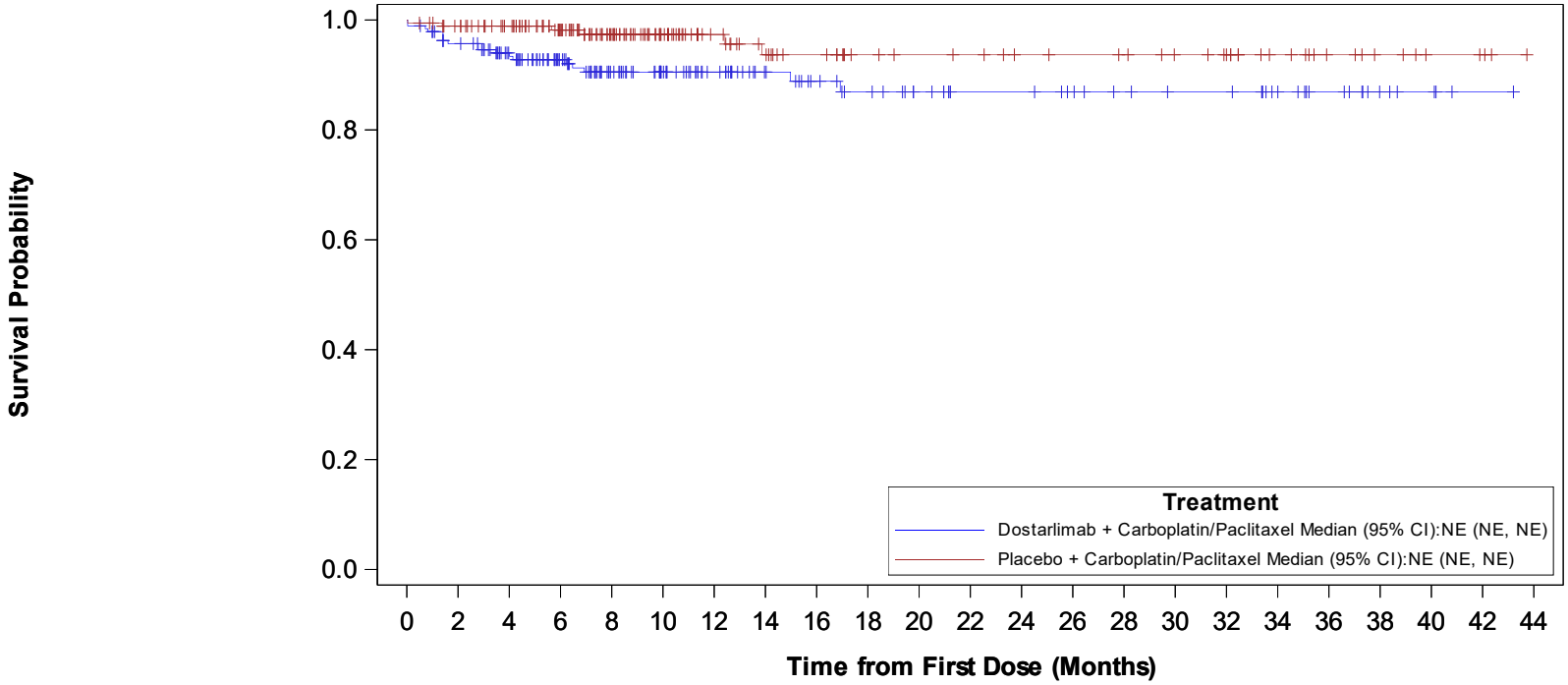
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	175(7)	156(9)	130(11)	105(14)	87(14)	72(14)	57(14)	51(15)	47(15)	41(15)	33(15)	33(15)	30(15)	27(15)	25(15)	24(16)	18(16)	13(16)	7(16)	3(16)	1(16)	0(16)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	168(7)	151(12)	126(14)	99(14)	75(14)	56(14)	48(14)	42(14)	35(14)	33(14)	32(14)	29(14)	28(14)	27(14)	23(15)	21(15)	14(15)	10(15)	7(15)	4(15)	3(15)	0(15)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression



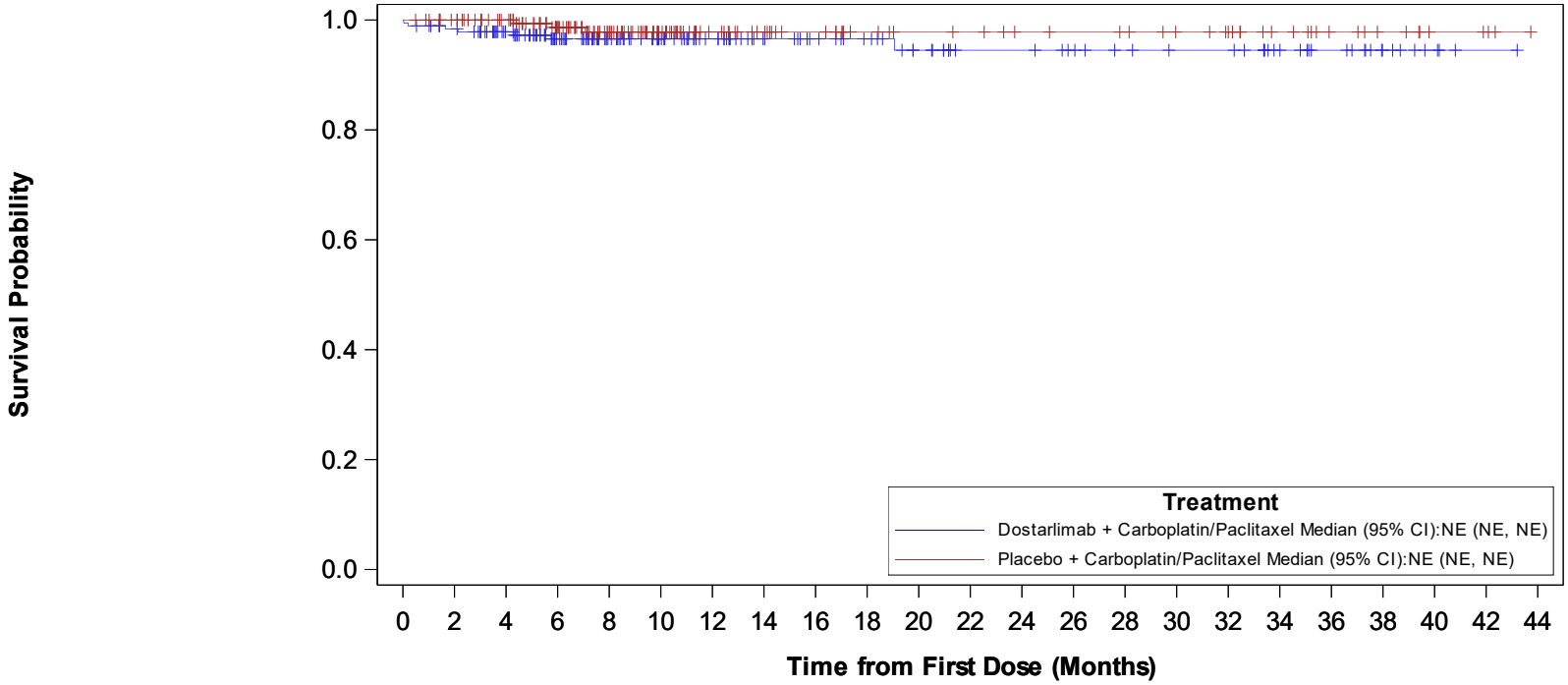
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	174(8)	154(11)	128(13)	102(16)	84(16)	69(16)	55(16)	48(17)	43(18)	37(18)	31(18)	31(18)	28(18)	25(18)	23(18)	23(18)	17(18)	12(18)	6(18)	4(18)	1(18)	0(18)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	172(2)	159(2)	133(3)	103(4)	77(4)	57(4)	48(6)	42(6)	35(6)	33(6)	32(6)	29(6)	28(6)	27(6)	24(6)	22(6)	15(6)	10(6)	7(6)	4(6)	3(6)	0(6)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Confusional state

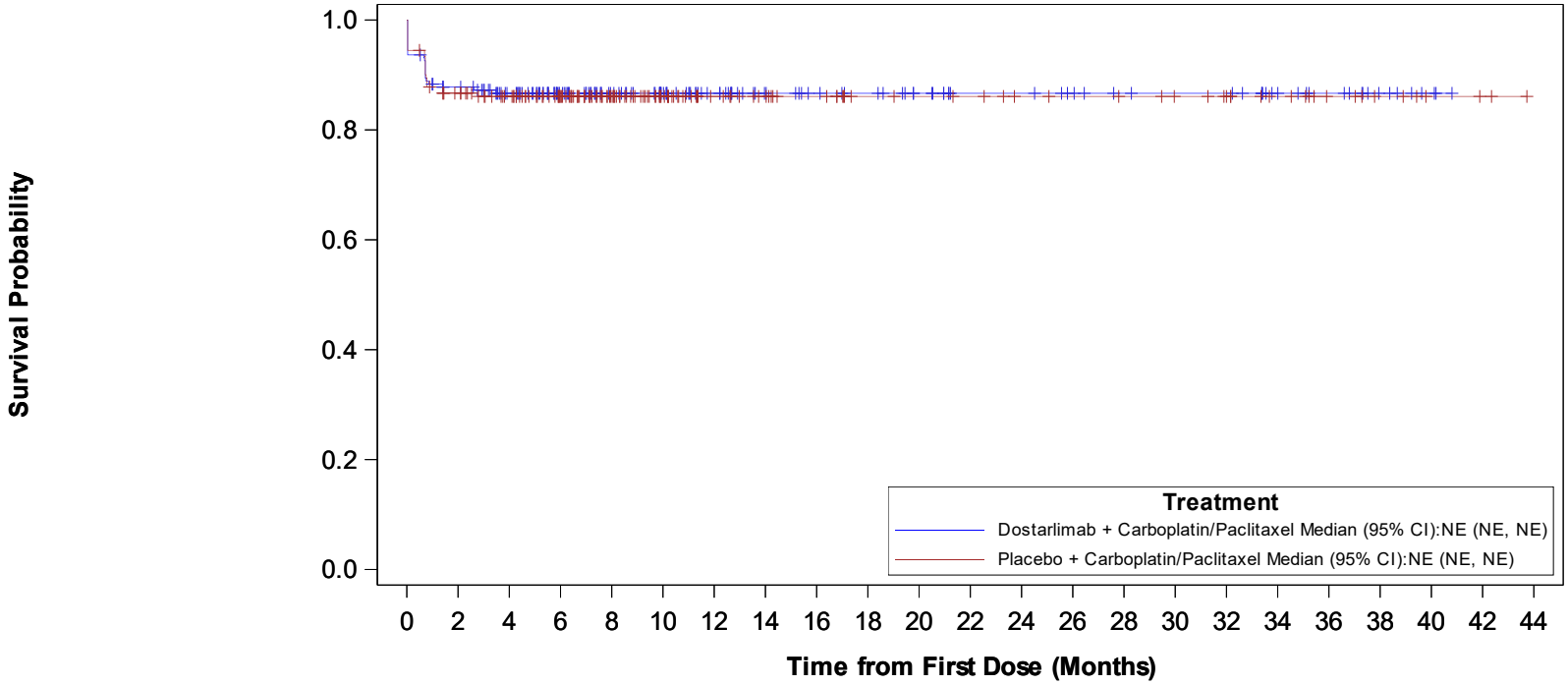


Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	180(3)	163(4)	135(6)	110(6)	91(6)	76(6)	61(6)	55(6)	50(6)	43(7)	35(7)	35(7)	32(7)	29(7)	27(7)	27(7)	20(7)	15(7)	8(7)	4(7)	1(7)	0(7)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	174(0)	161(0)	133(2)	104(3)	80(3)	58(3)	50(3)	44(3)	37(3)	34(3)	33(3)	30(3)	29(3)	28(3)	25(3)	23(3)	16(3)	11(3)	8(3)	4(3)	3(3)	0(3)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Injury, poisoning and procedural complications
Preferred Term: Infusion related reaction



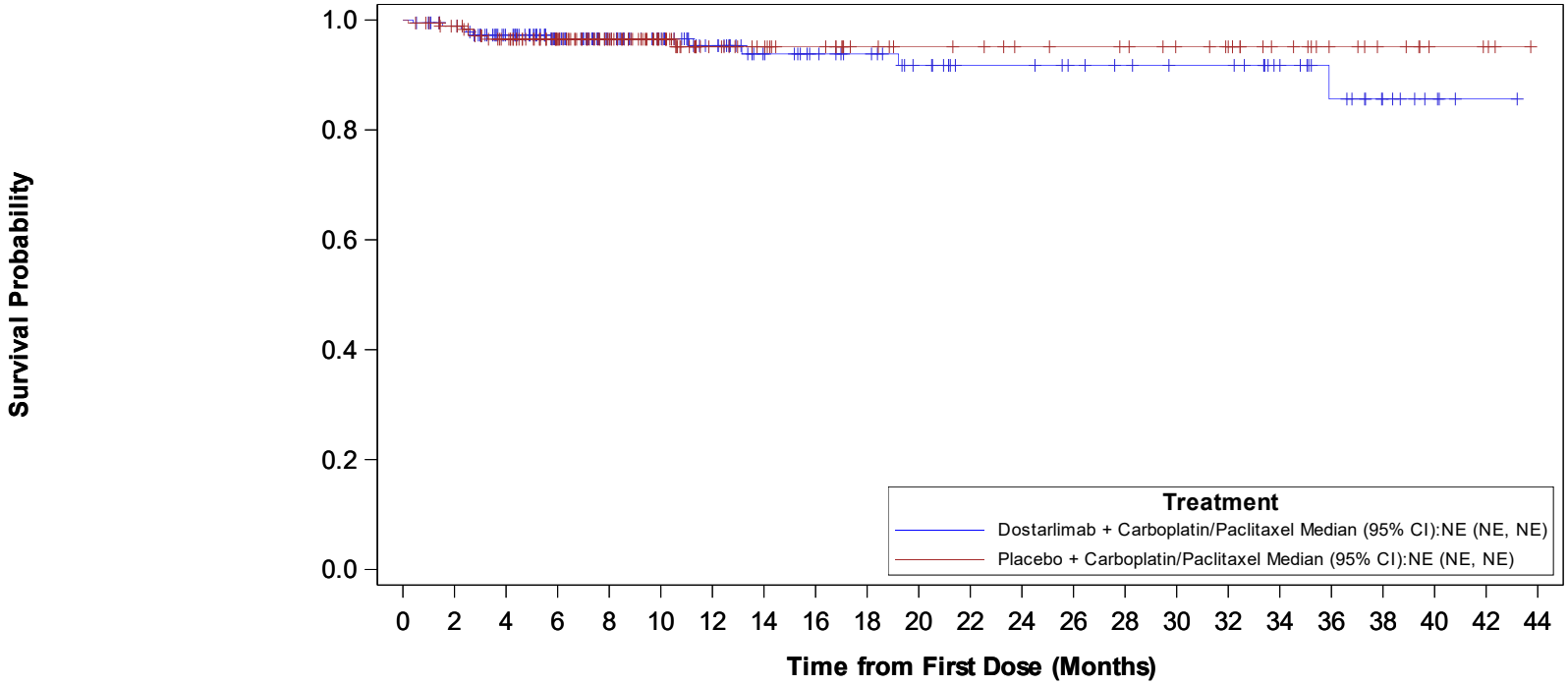
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	160(23)	143(25)	116(25)	95(25)	79(25)	65(25)	52(25)	47(25)	44(25)	38(25)	31(25)	31(25)	28(25)	25(25)	24(25)	24(25)	17(25)	13(25)	7(25)	3(25)	0(25)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	151(24)	138(25)	117(25)	88(25)	65(25)	48(25)	42(25)	37(25)	30(25)	29(25)	28(25)	25(25)	24(25)	23(25)	21(25)	19(25)	14(25)	9(25)	6(25)	3(25)	2(25)	0(25)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Injury, poisoning and procedural complications
Preferred Term: Fall



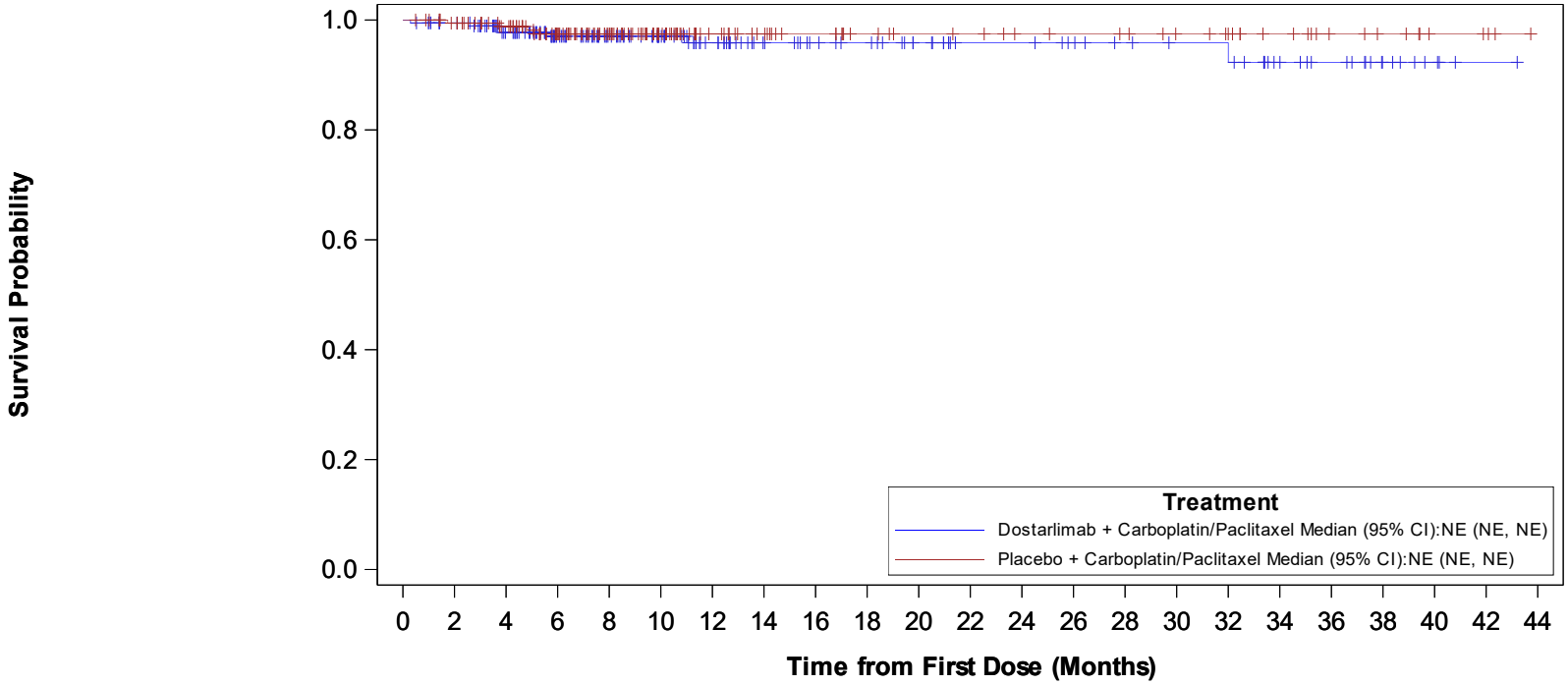
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	180(2)	161(5)	133(6)	107(6)	88(6)	73(7)	58(8)	52(8)	48(8)	41(9)	34(9)	34(9)	31(9)	29(9)	27(9)	27(9)	20(9)	14(10)	8(10)	4(10)	1(10)	0(10)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	172(2)	155(6)	130(6)	103(6)	78(6)	56(7)	49(7)	44(7)	37(7)	34(7)	33(7)	30(7)	29(7)	28(7)	25(7)	23(7)	16(7)	11(7)	8(7)	4(7)	3(7)	0(7)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Injury, poisoning and procedural complications
Preferred Term: Contusion



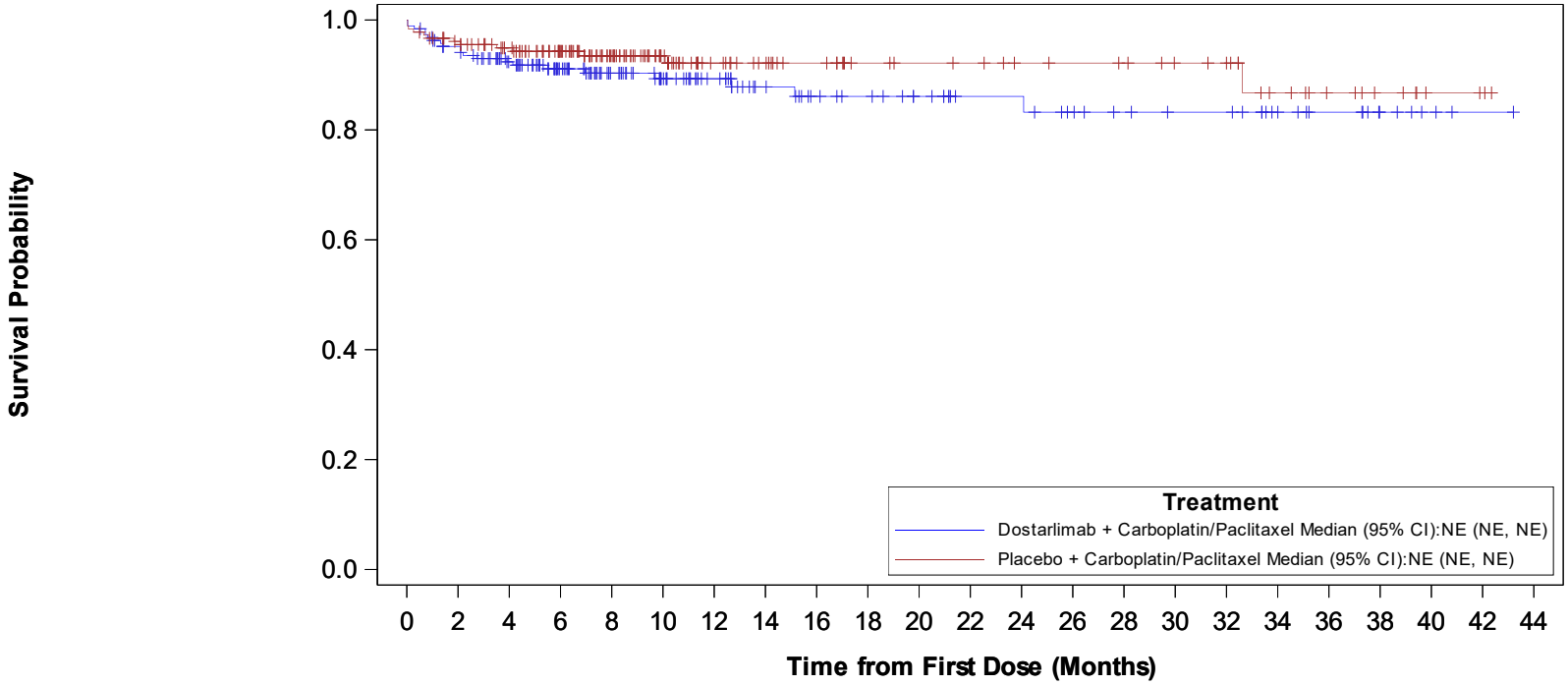
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	181(1)	161(4)	132(5)	109(5)	90(5)	74(6)	59(6)	53(6)	50(6)	43(6)	35(6)	35(6)	32(6)	29(6)	27(6)	27(7)	19(7)	15(7)	8(7)	4(7)	1(7)	0(7)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	173(1)	159(2)	131(4)	102(4)	76(4)	55(4)	47(4)	41(4)	35(4)	32(4)	31(4)	28(4)	27(4)	26(4)	23(4)	21(4)	15(4)	10(4)	8(4)	4(4)	3(4)	0(4)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders
Preferred Term: Hypertension



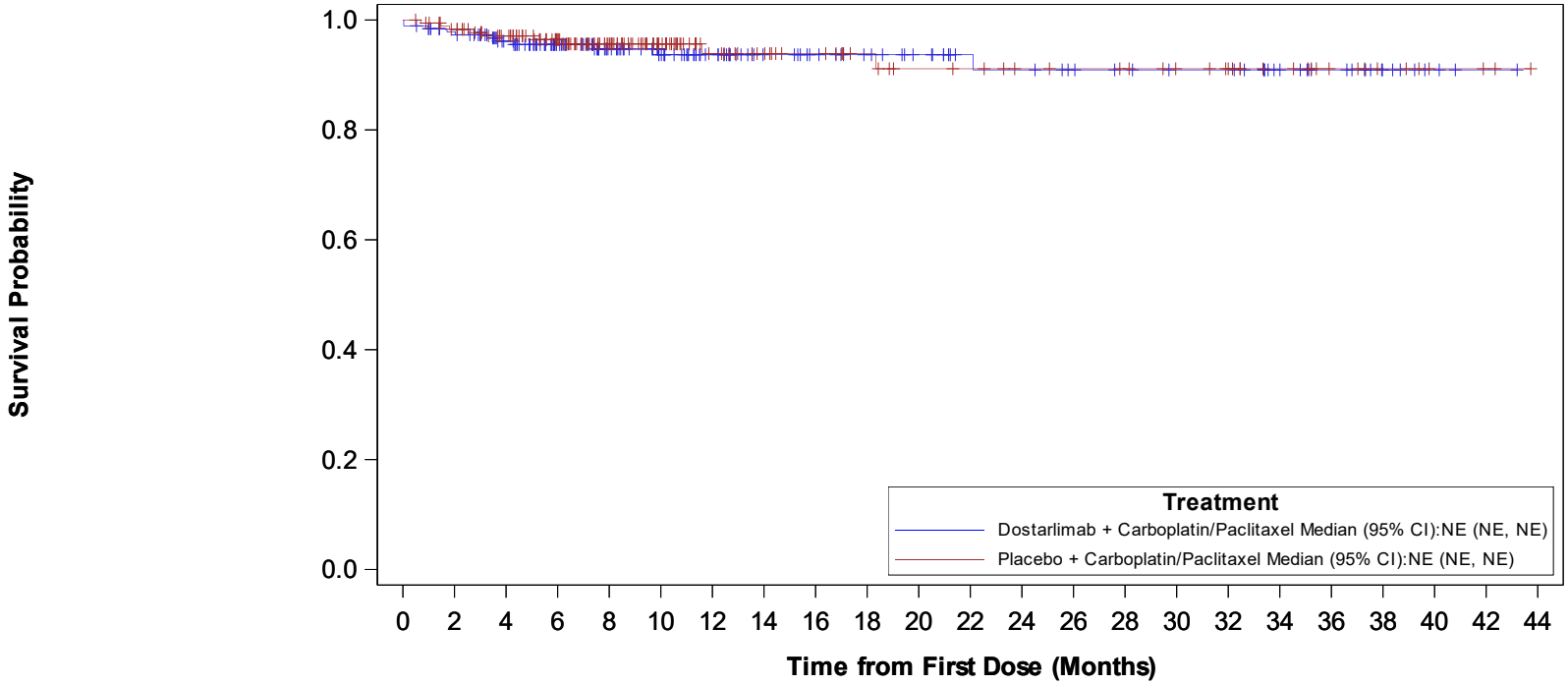
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	173(9)	152(14)	124(16)	98(17)	81(18)	66(18)	52(19)	45(20)	42(20)	37(20)	30(20)	30(20)	26(21)	23(21)	21(21)	21(21)	15(21)	11(21)	6(21)	3(21)	1(21)	0(21)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	167(7)	153(9)	128(10)	98(11)	72(11)	53(12)	46(12)	40(12)	33(12)	31(12)	30(12)	27(12)	26(12)	25(12)	22(12)	21(12)	14(13)	10(13)	7(13)	3(13)	2(13)	0(13)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders
Preferred Term: Hot flush



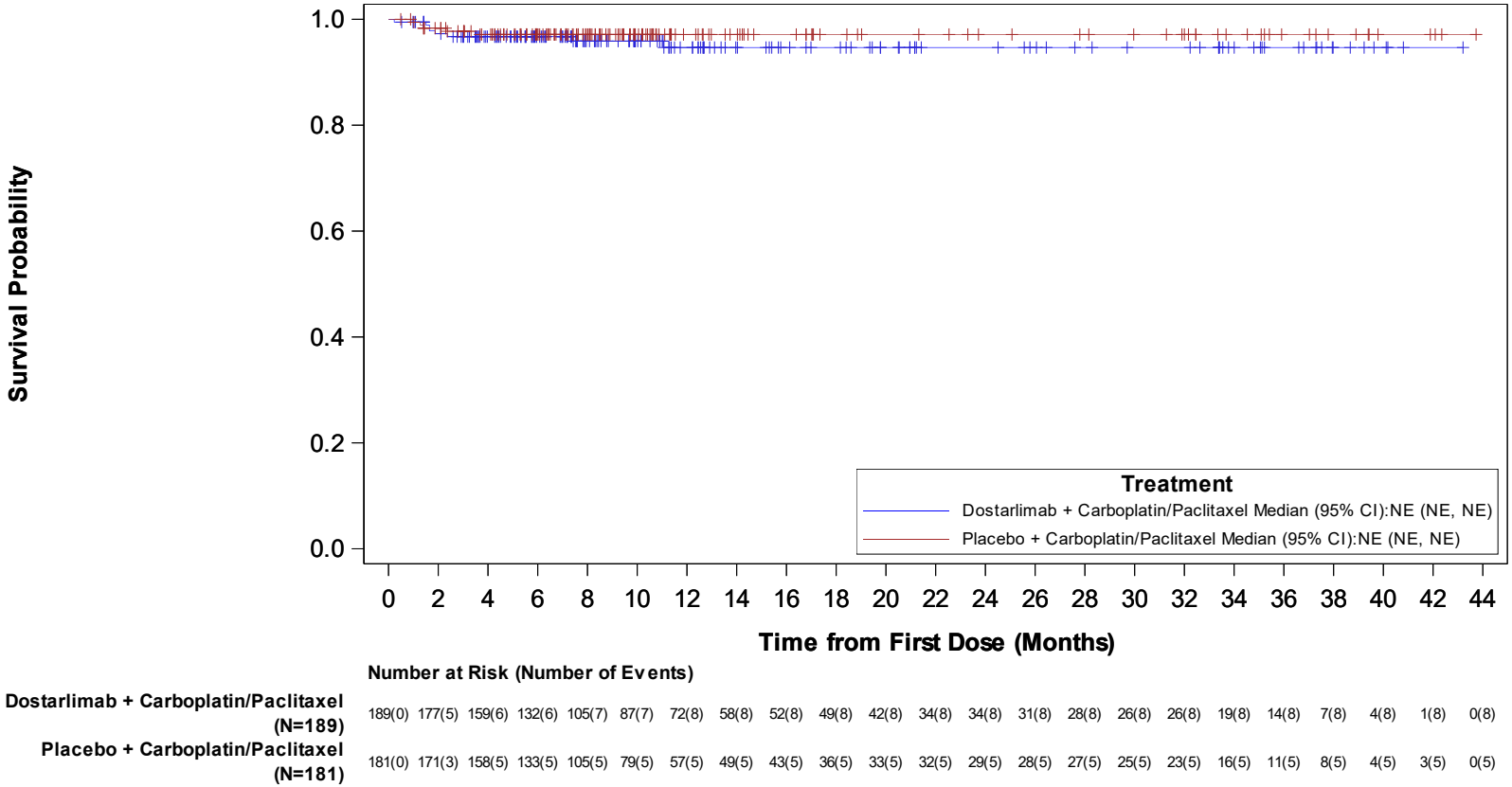
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	178(4)	159(7)	132(8)	107(9)	88(10)	72(10)	57(10)	52(10)	47(10)	42(10)	34(10)	33(11)	30(11)	28(11)	26(11)	26(11)	19(11)	14(11)	7(11)	3(11)	1(11)	0(11)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	171(3)	156(5)	129(6)	100(7)	74(7)	52(8)	45(8)	40(8)	34(8)	30(9)	29(9)	26(9)	25(9)	24(9)	21(9)	19(9)	14(9)	9(9)	6(9)	3(9)	2(9)	0(9)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

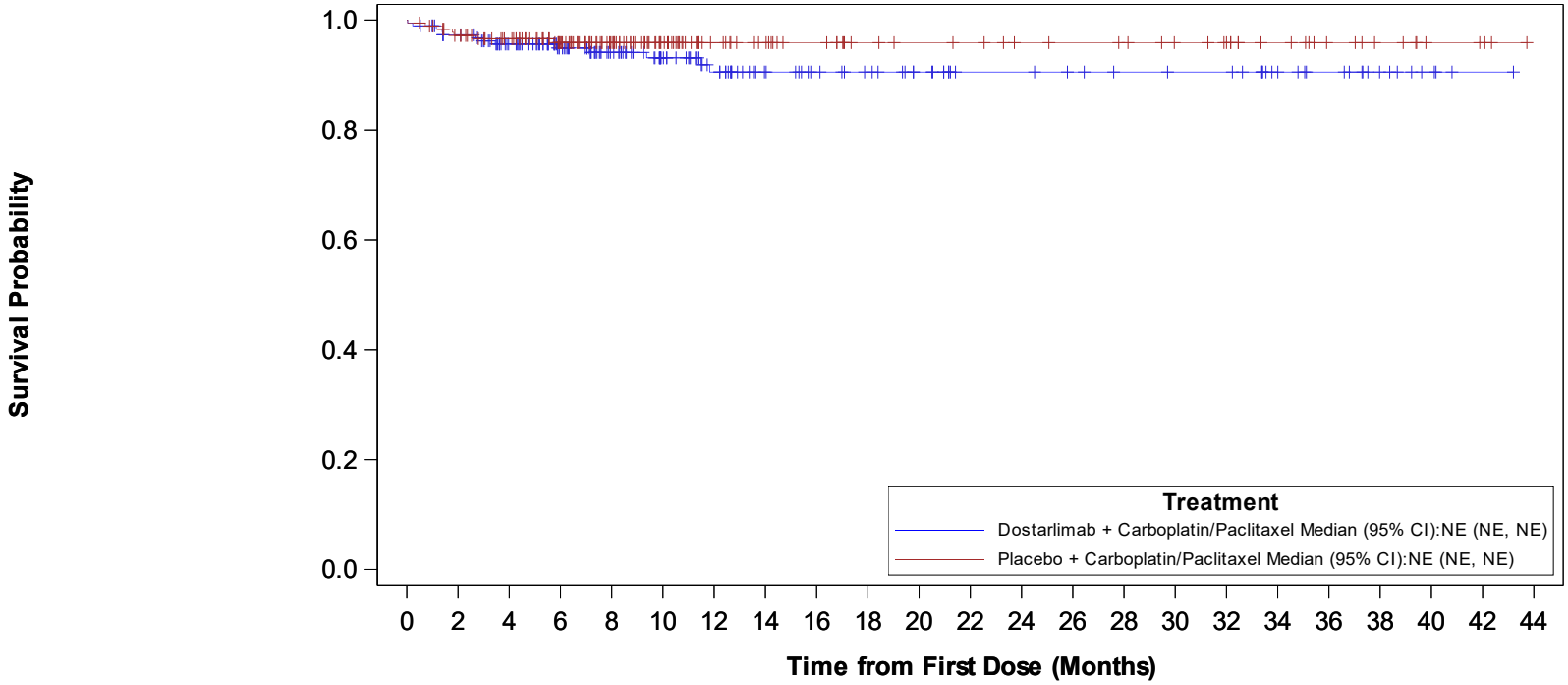
System Organ Class: Vascular disorders
Preferred Term: Hypotension



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Dysuria



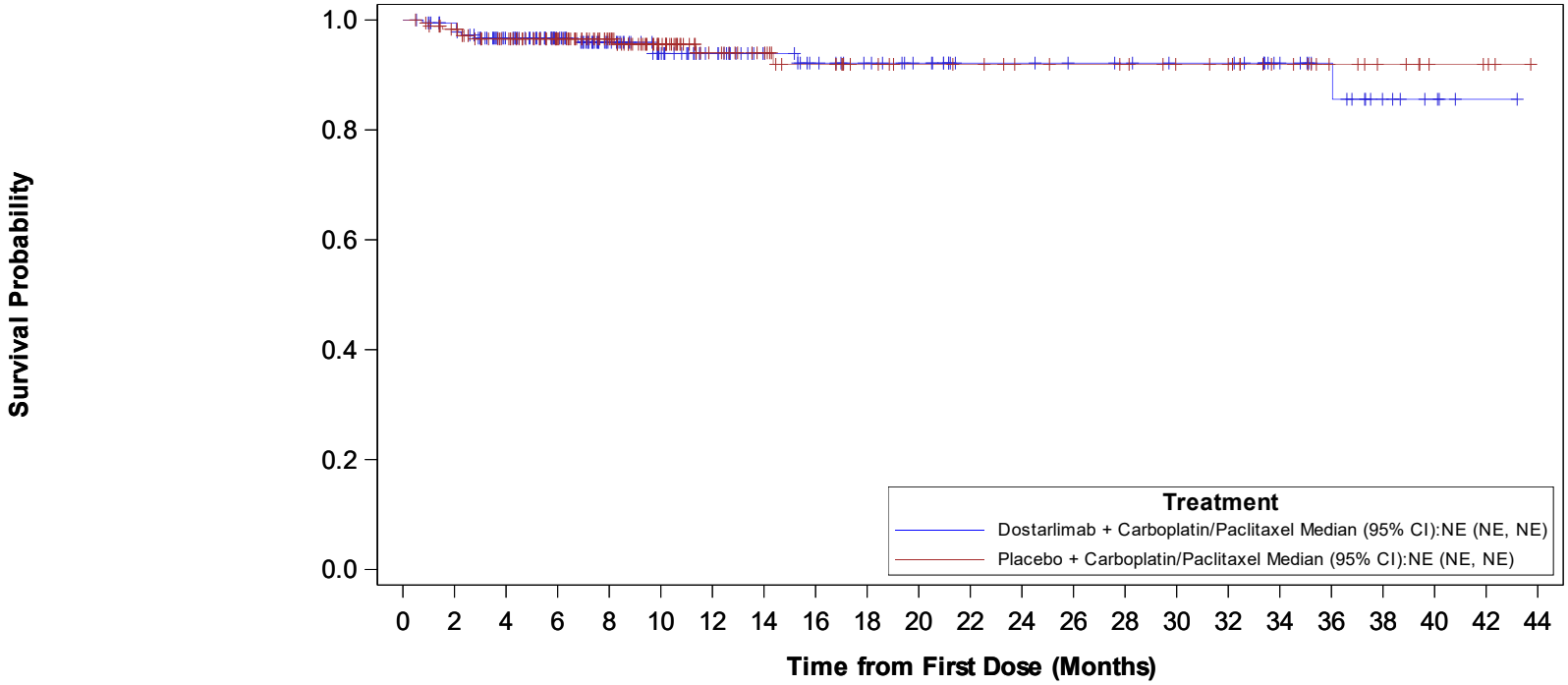
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	177(5)	157(8)	129(9)	105(10)	85(11)	69(13)	54(13)	48(13)	44(13)	38(13)	30(13)	30(13)	28(13)	26(13)	25(13)	25(13)	18(13)	14(13)	8(13)	4(13)	1(13)	0(13)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	169(5)	155(6)	129(7)	101(7)	76(7)	55(7)	48(7)	42(7)	35(7)	33(7)	32(7)	29(7)	28(7)	27(7)	24(7)	22(7)	16(7)	11(7)	8(7)	4(7)	3(7)	0(7)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Urinary incontinence



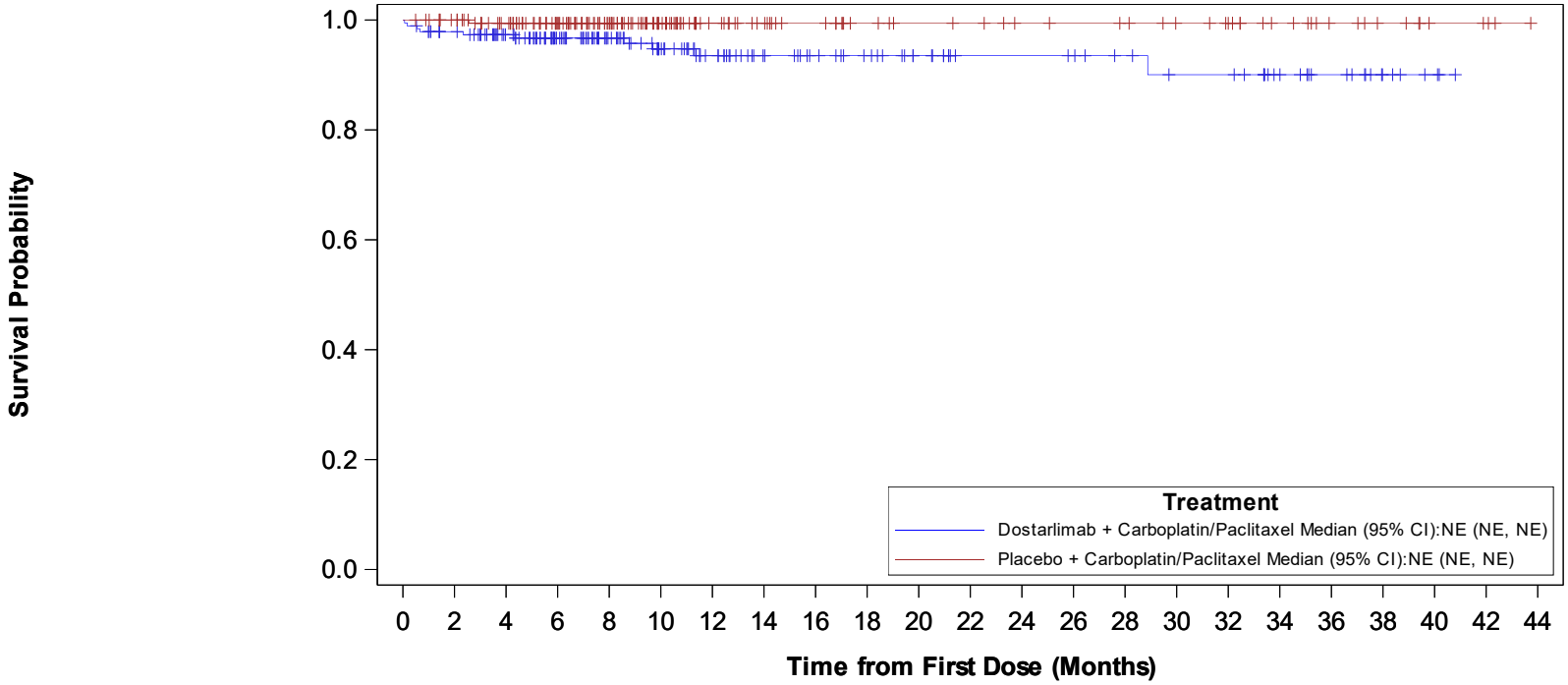
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	181(1)	159(6)	132(6)	105(7)	85(9)	70(9)	56(9)	49(10)	44(10)	39(10)	31(10)	31(10)	29(10)	28(10)	26(10)	26(10)	19(10)	14(10)	7(11)	4(11)	1(11)	0(11)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	171(3)	155(6)	130(6)	104(6)	78(7)	56(8)	49(8)	42(9)	36(9)	33(9)	32(9)	29(9)	28(9)	27(9)	24(9)	23(9)	16(9)	11(9)	8(9)	4(9)	3(9)	0(9)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Pollakiuria



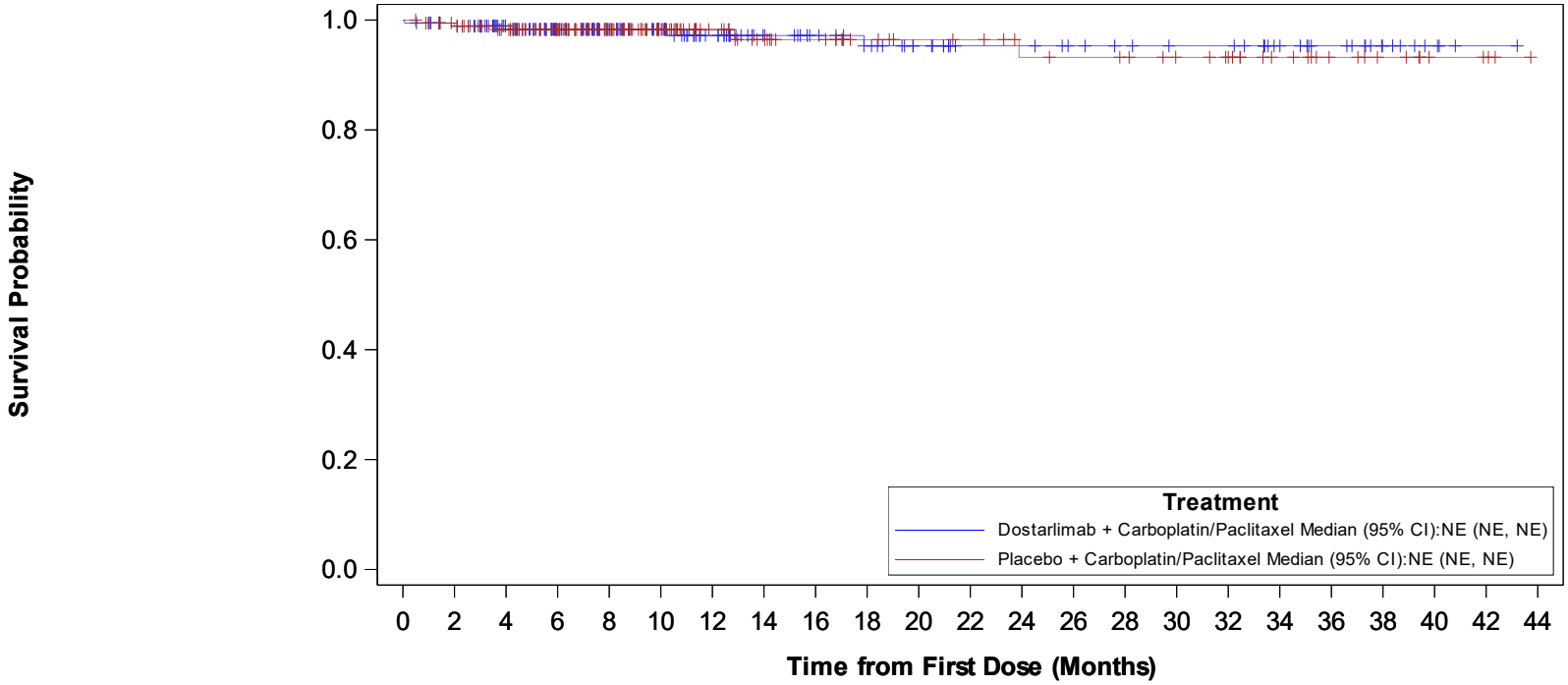
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	178(4)	160(5)	132(6)	108(6)	87(8)	71(9)	58(9)	52(9)	47(9)	40(9)	32(9)	32(9)	31(9)	28(9)	25(10)	25(10)	18(10)	13(10)	6(10)	3(10)	0(10)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	174(0)	160(1)	135(1)	106(1)	80(1)	58(1)	50(1)	44(1)	37(1)	34(1)	33(1)	30(1)	29(1)	28(1)	25(1)	23(1)	16(1)	11(1)	8(1)	4(1)	3(1)	0(1)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Haematuria



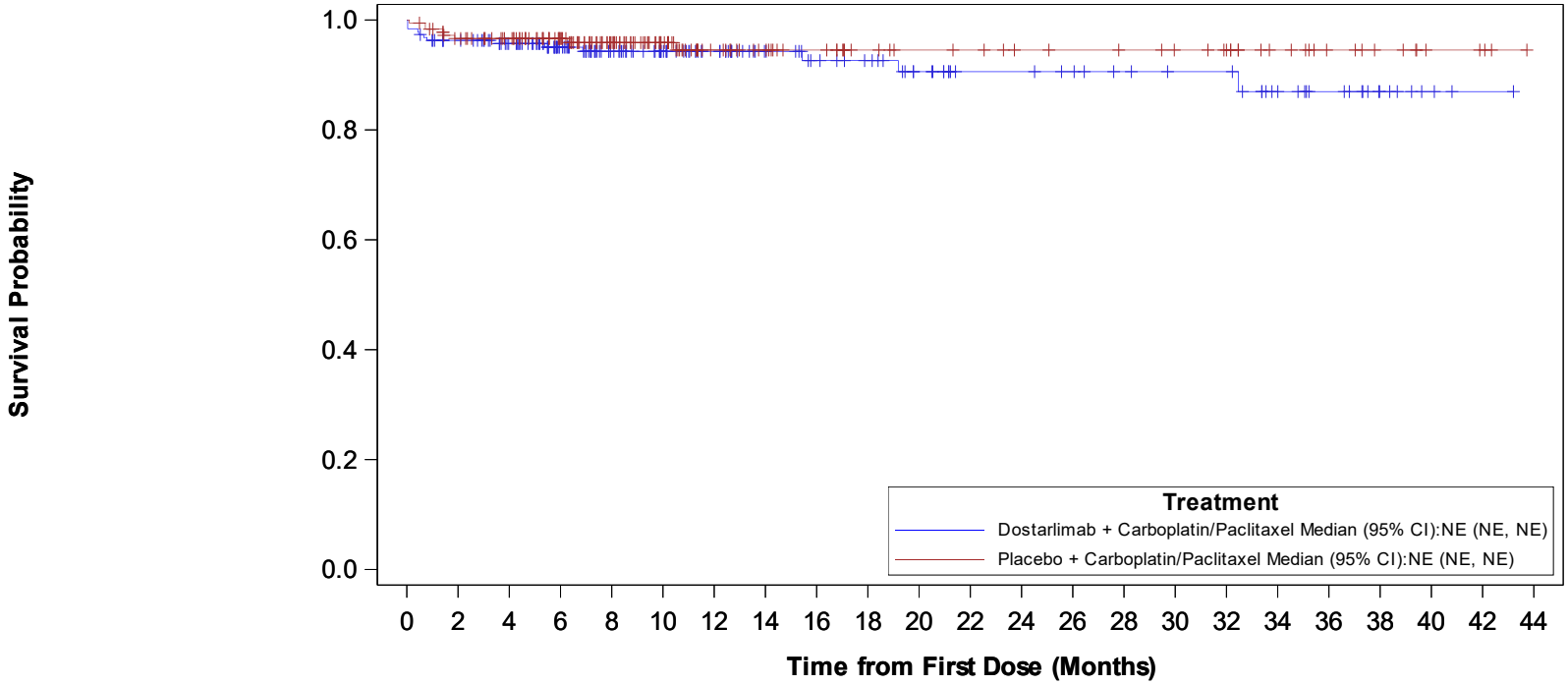
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	180(2)	163(2)	135(3)	110(3)	91(3)	75(4)	60(4)	54(4)	49(5)	42(5)	34(5)	34(5)	31(5)	29(5)	27(5)	27(5)	20(5)	15(5)	8(5)	4(5)	1(5)	0(5)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	173(1)	158(3)	132(3)	105(3)	80(3)	58(3)	49(4)	44(4)	37(4)	34(4)	33(4)	29(5)	28(5)	27(5)	24(5)	22(5)	16(5)	11(5)	8(5)	4(5)	3(5)	0(5)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Reproductive system and breast disorders
Preferred Term: Vaginal haemorrhage



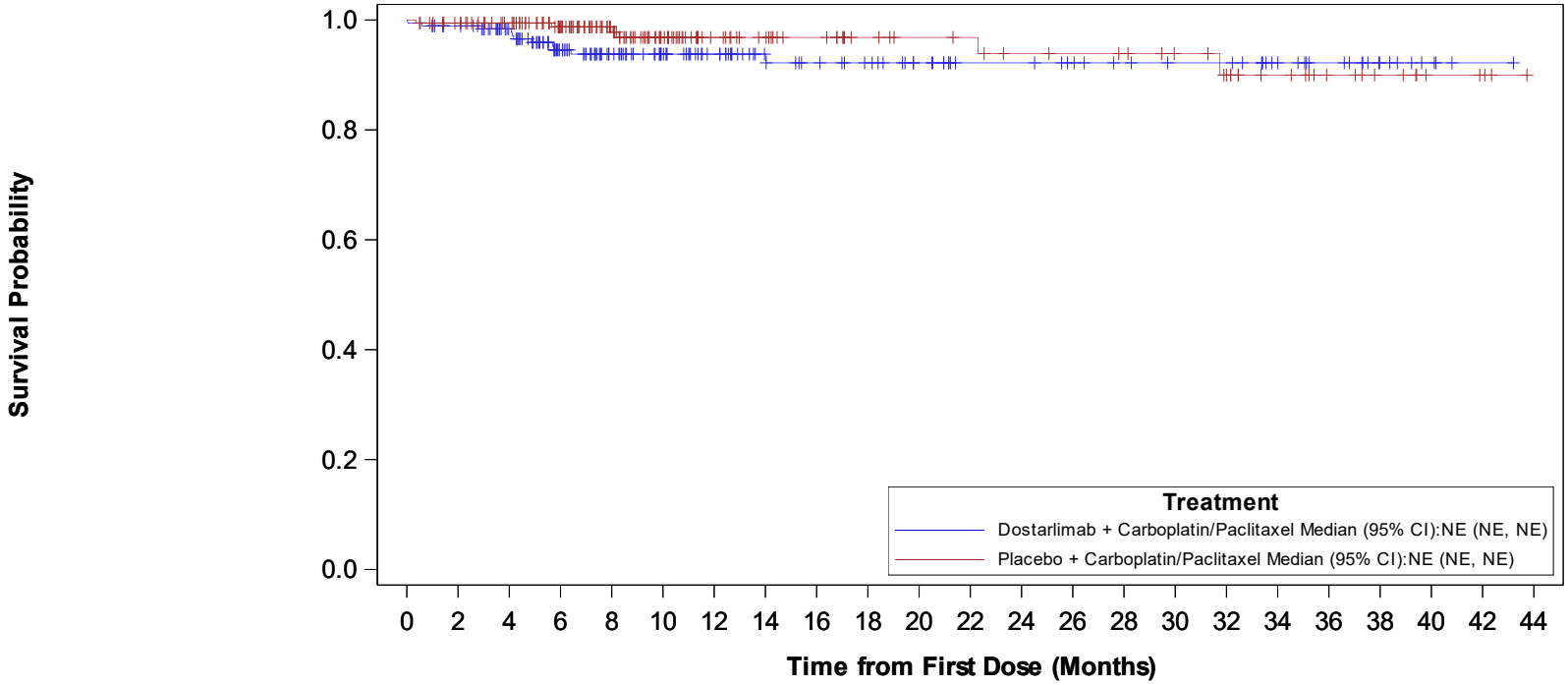
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	175(7)	160(8)	131(9)	107(10)	89(10)	75(10)	60(10)	53(11)	49(11)	41(12)	33(12)	33(12)	31(12)	28(12)	26(12)	26(12)	19(13)	14(13)	7(13)	3(13)	1(13)	0(13)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	168(6)	157(6)	133(6)	104(7)	78(7)	57(8)	49(8)	43(8)	36(8)	33(8)	32(8)	29(8)	28(8)	27(8)	25(8)	23(8)	16(8)	11(8)	8(8)	4(8)	3(8)	0(8)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Reproductive system and breast disorders
Preferred Term: Pelvic pain



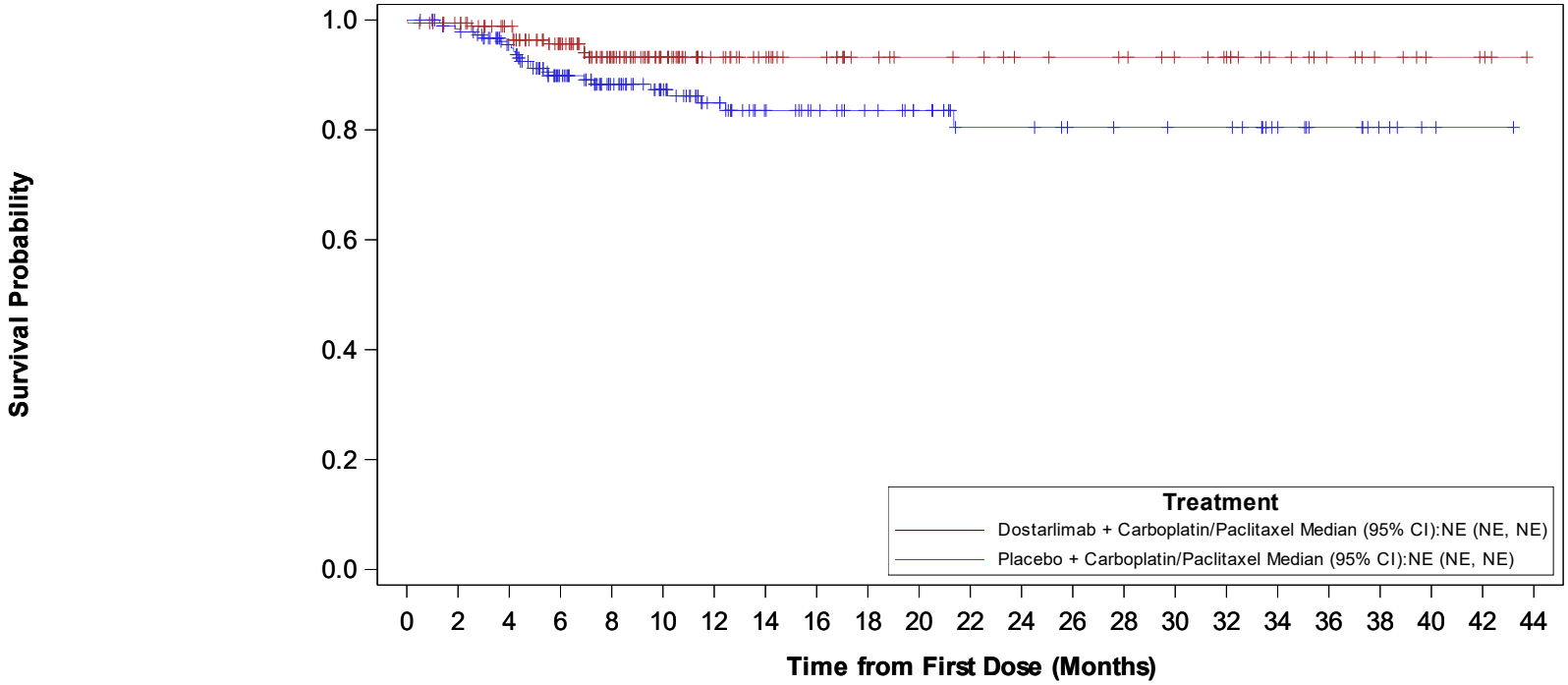
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	180(2)	162(3)	129(9)	106(10)	88(10)	74(10)	59(10)	54(11)	50(11)	43(11)	35(11)	35(11)	32(11)	29(11)	27(11)	27(11)	20(11)	15(11)	8(11)	4(11)	1(11)	0(11)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	173(1)	160(1)	134(2)	105(2)	78(4)	57(4)	50(4)	44(4)	37(4)	34(4)	33(4)	30(5)	29(5)	28(5)	25(5)	22(6)	16(6)	11(6)	8(6)	4(6)	3(6)	0(6)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism



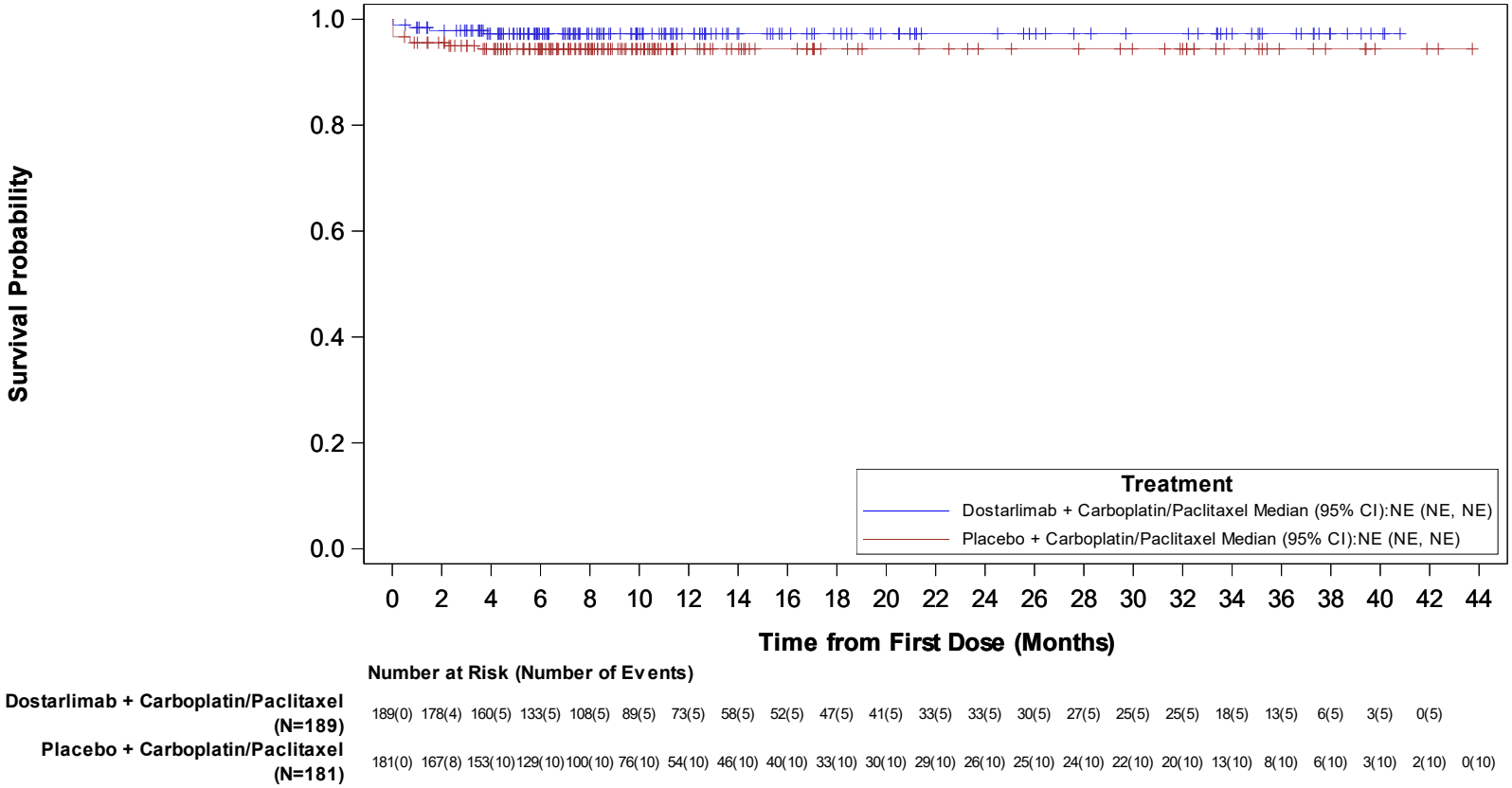
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	179(3)	158(8)	124(17)	99(19)	81(20)	64(22)	50(23)	44(23)	39(23)	34(23)	25(24)	25(24)	22(24)	21(24)	20(24)	20(24)	13(24)	9(24)	5(24)	2(24)	1(24)	0(24)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	173(1)	159(2)	131(7)	100(10)	75(10)	55(10)	47(10)	41(10)	34(10)	31(10)	30(10)	27(10)	26(10)	25(10)	22(10)	20(10)	14(10)	10(10)	7(10)	4(10)	3(10)	0(10)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

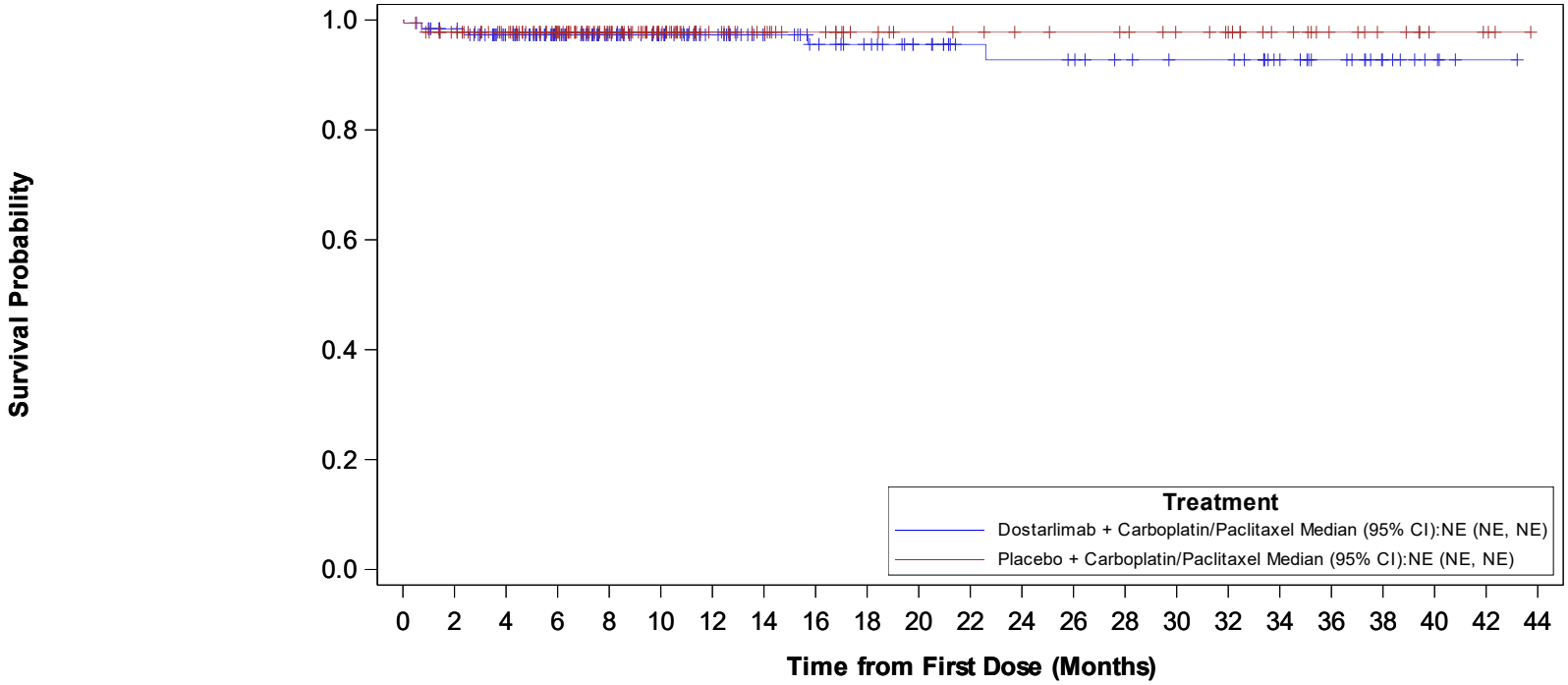
System Organ Class: Immune system disorders
Preferred Term: Drug hypersensitivity



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Immune system disorders
Preferred Term: Hypersensitivity



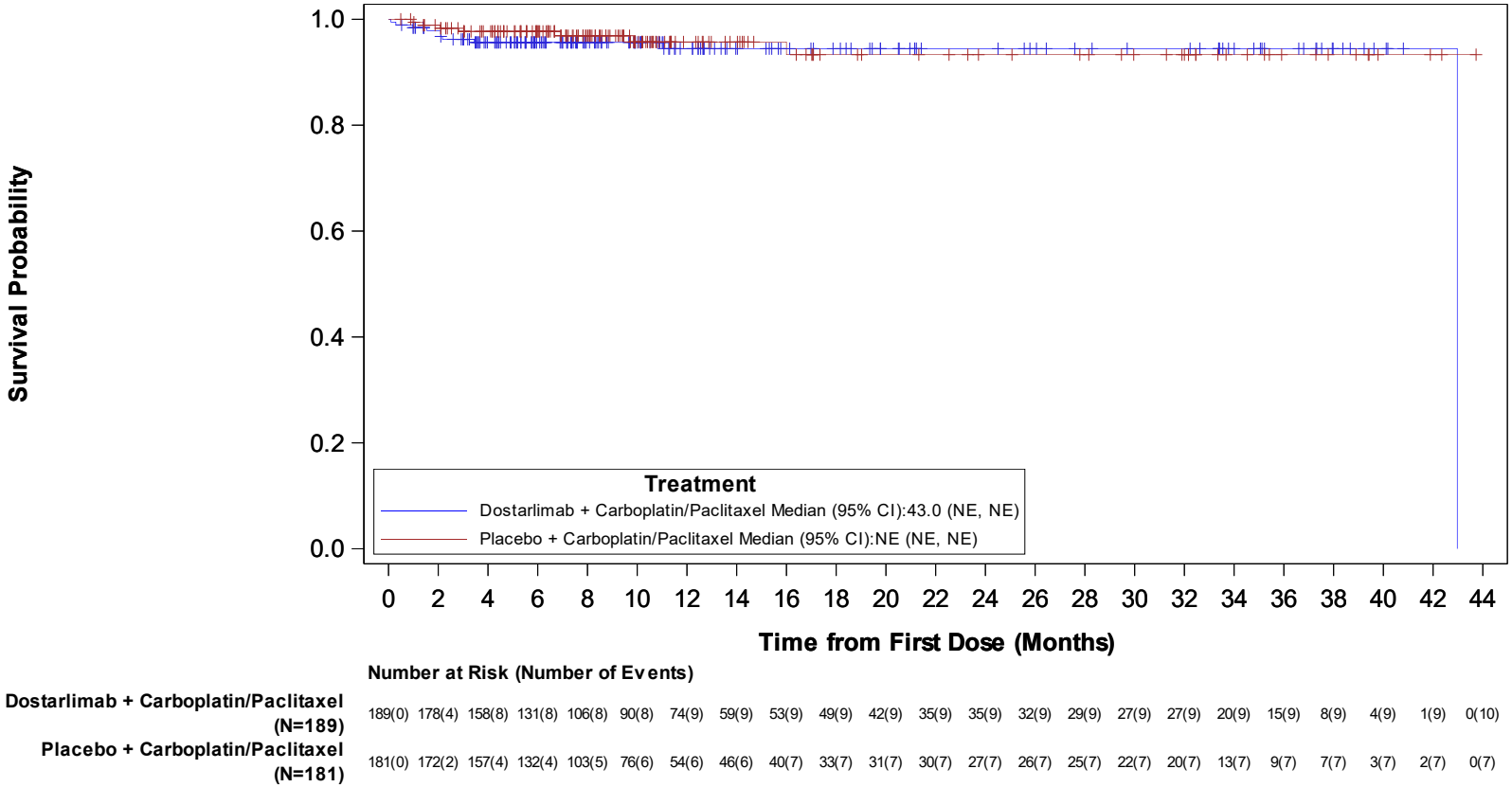
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	179(3)	163(5)	135(5)	110(5)	91(5)	75(5)	61(5)	54(6)	49(6)	42(6)	34(6)	33(7)	32(7)	29(7)	27(7)	27(7)	20(7)	15(7)	8(7)	4(7)	1(7)	0(7)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	170(4)	157(4)	132(4)	103(4)	78(4)	56(4)	48(4)	42(4)	36(4)	33(4)	32(4)	30(4)	29(4)	28(4)	25(4)	23(4)	16(4)	11(4)	8(4)	4(4)	3(4)	0(4)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

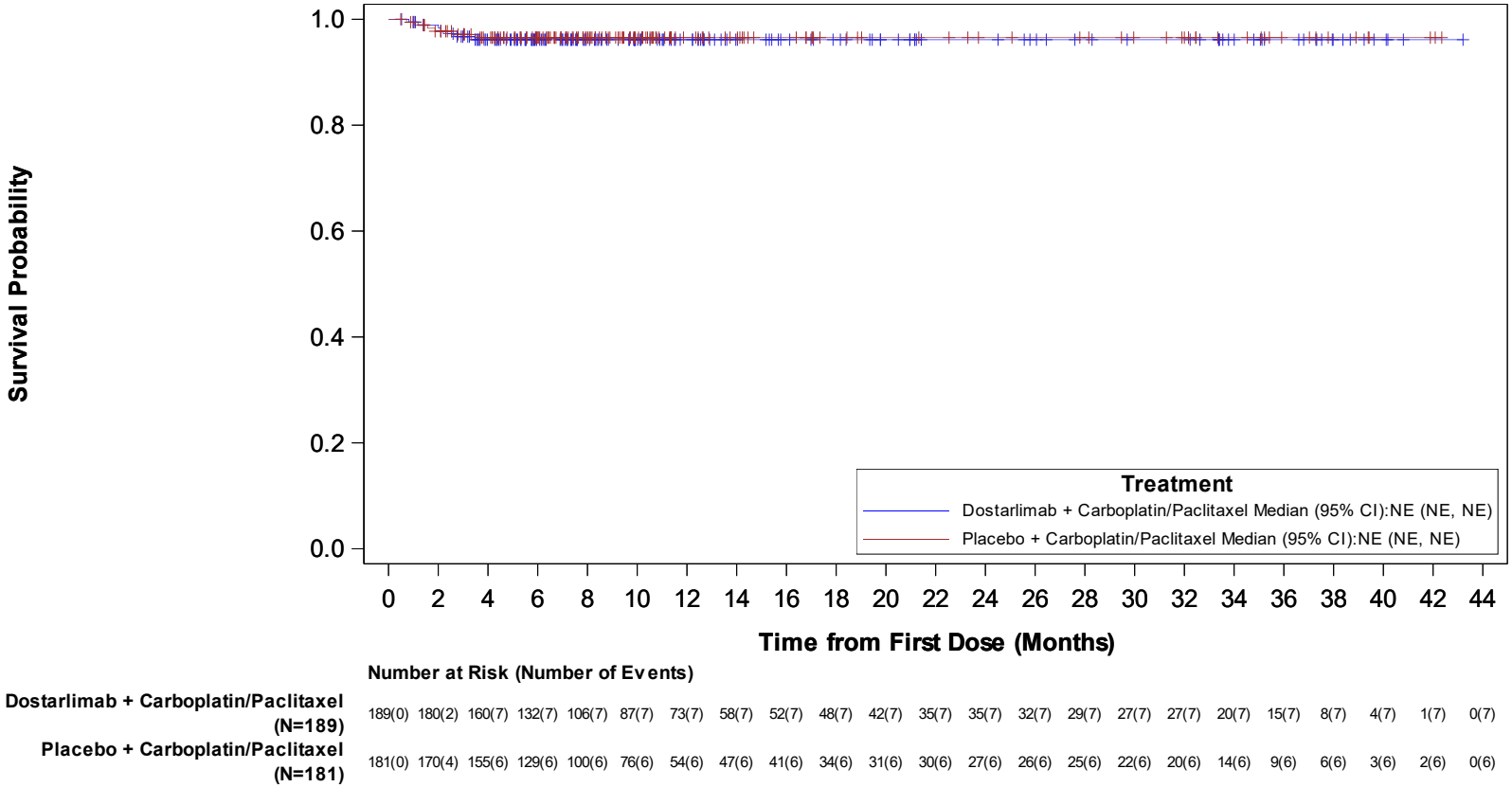
System Organ Class: Cardiac disorders
Preferred Term: Palpitations



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

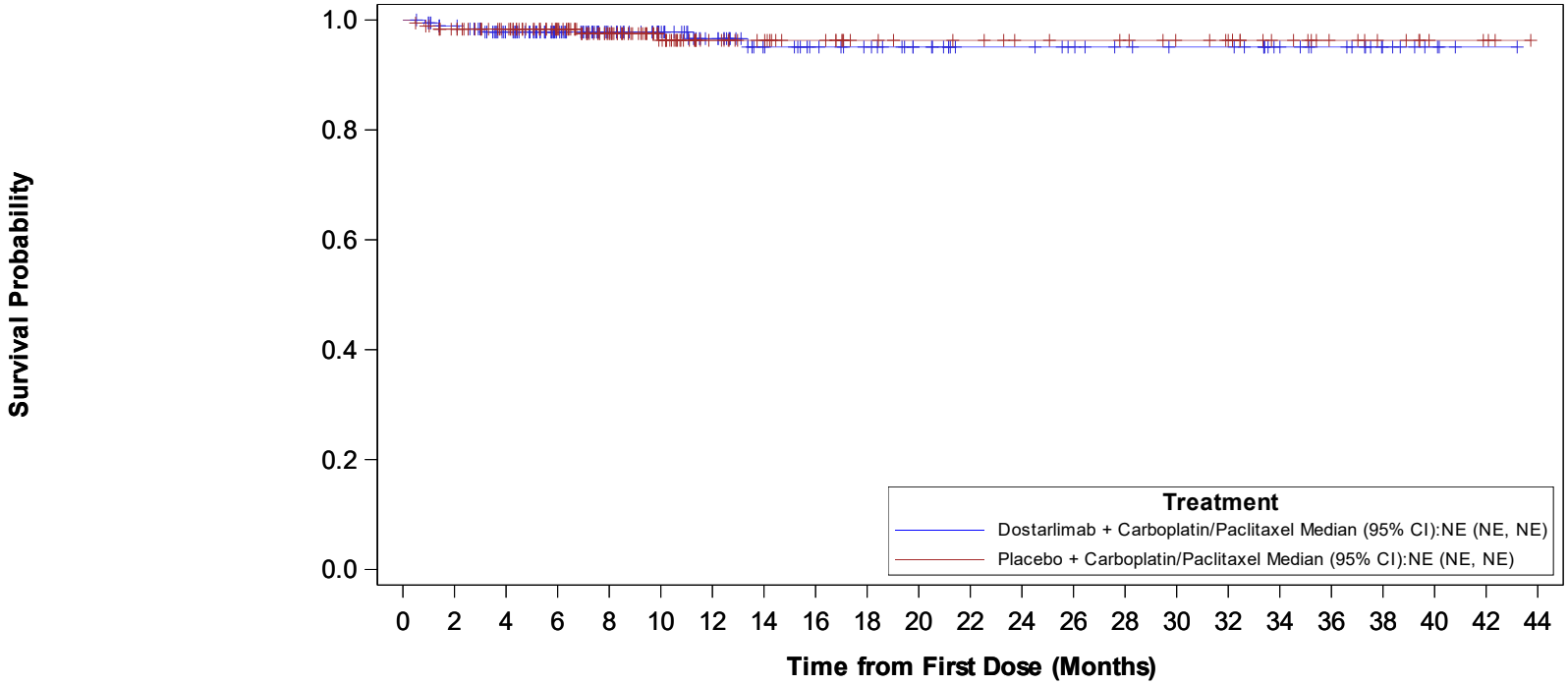
System Organ Class: Eye disorders
Preferred Term: Vision blurred



Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Ear and labyrinth disorders
Preferred Term: Tinnitus



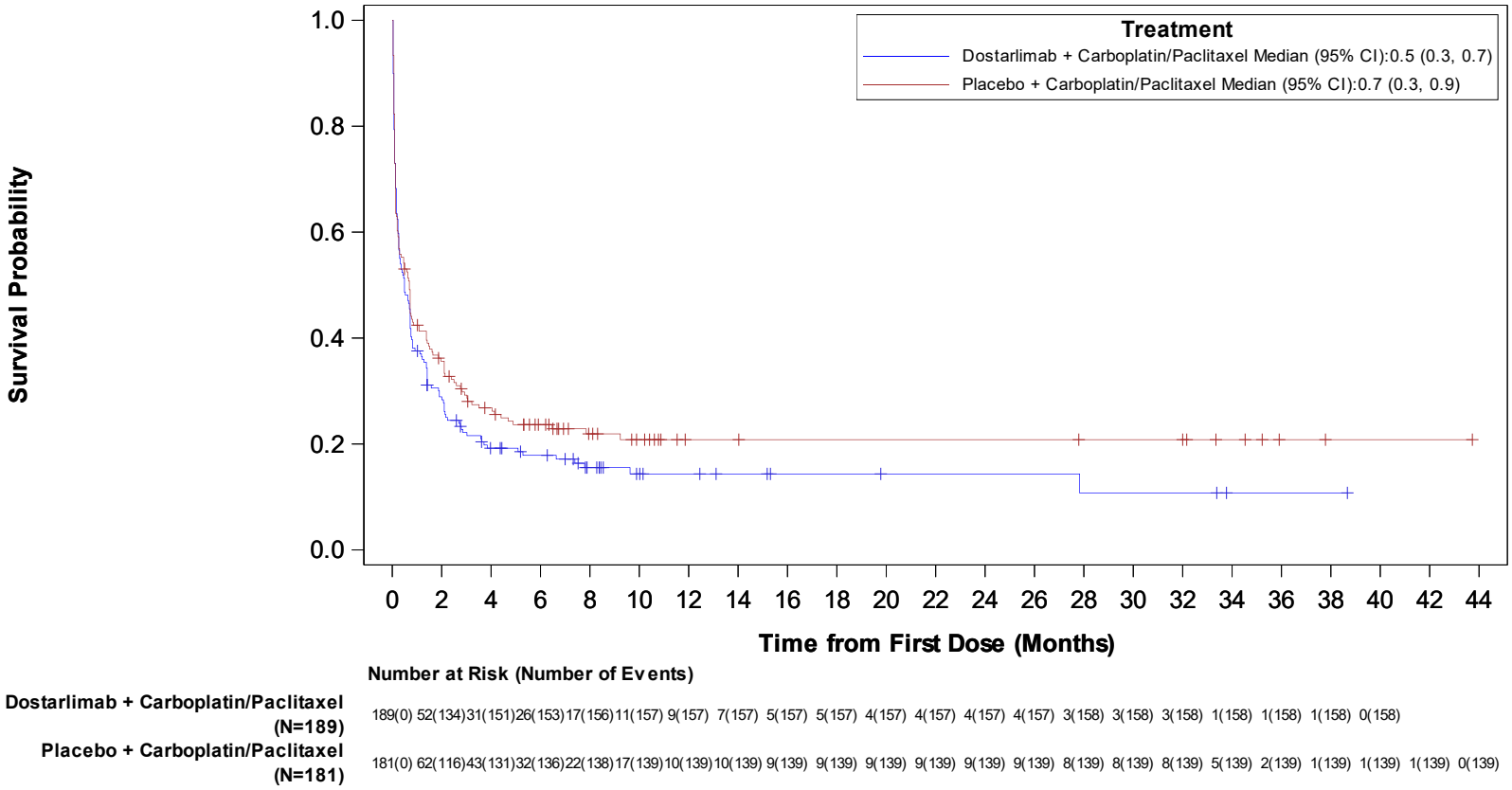
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	180(2)	162(4)	134(4)	108(4)	91(4)	74(5)	58(6)	52(6)	48(6)	41(6)	34(6)	34(6)	31(6)	28(6)	26(6)	26(6)	19(6)	15(6)	8(6)	4(6)	1(6)	0(6)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	171(3)	158(3)	133(3)	105(4)	78(5)	56(5)	49(5)	43(5)	36(5)	34(5)	33(5)	30(5)	29(5)	28(5)	25(5)	23(5)	16(5)	11(5)	8(5)	4(5)	3(5)	0(5)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_0502_km_ae_socpt.sas, Output: f_3_0502_km_ae_socpt.rtf, Generated on: 19SEP2024 15:40,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects

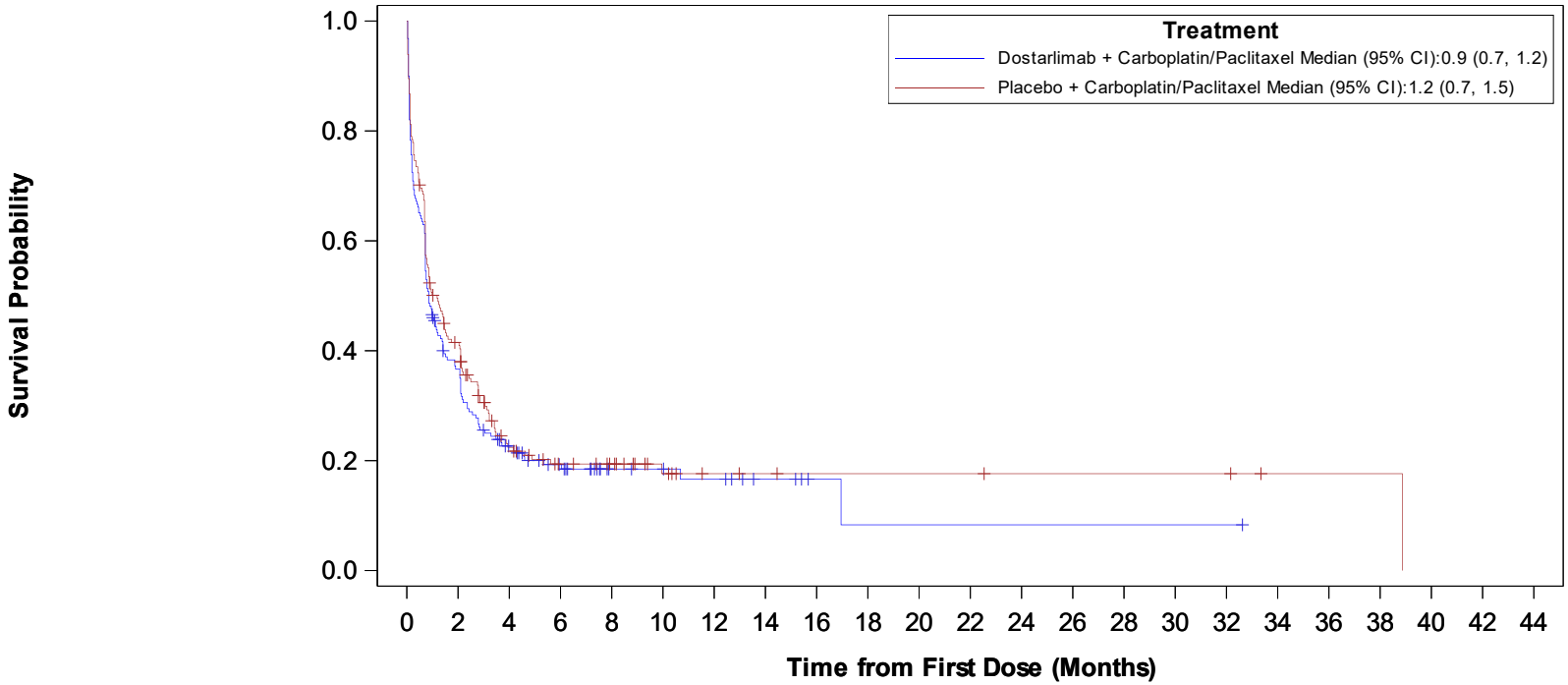
System Organ Class: Gastrointestinal disorders



NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders

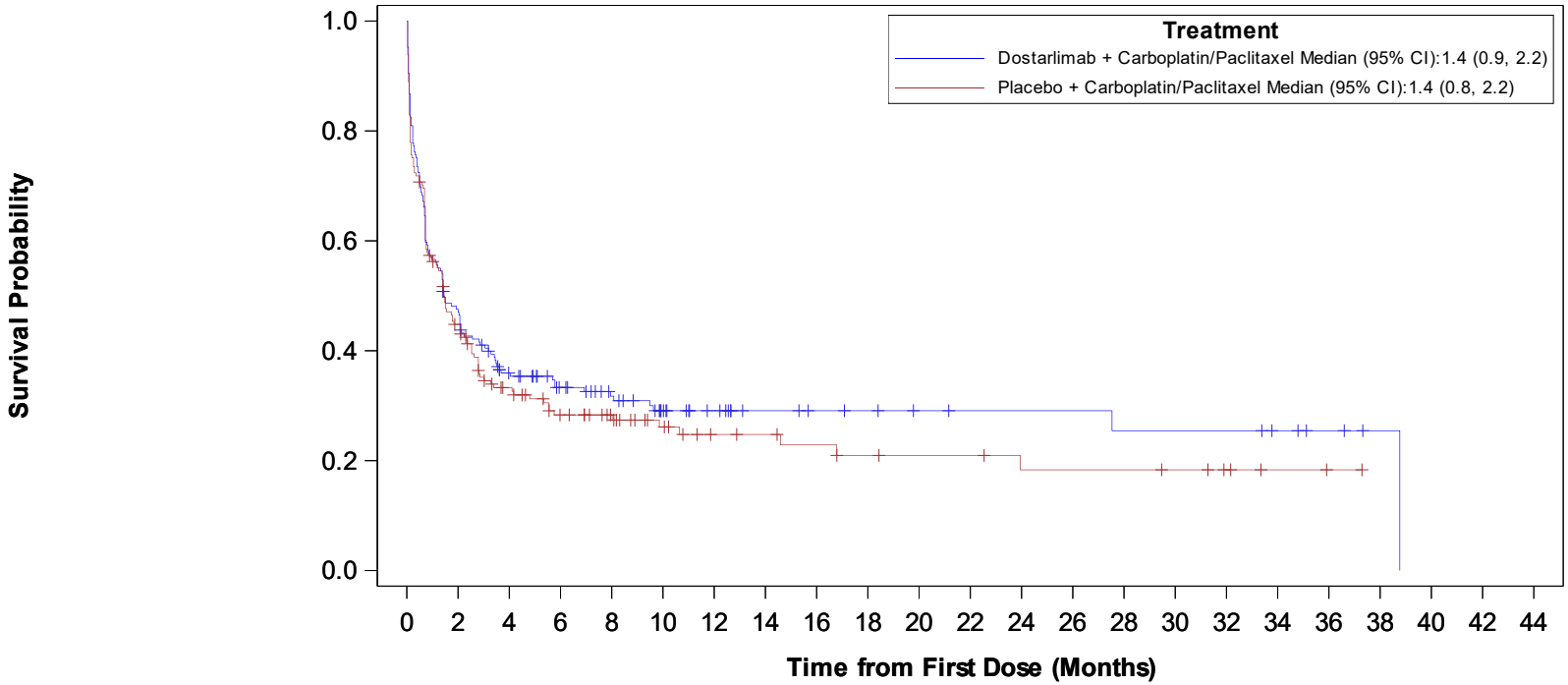


Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0) 66(119) 36(144) 24(149) 12(150) 11(150) 9(151) 5(151) 2(151) 1(152) 1(152) 1(152) 1(152) 1(152) 1(152) 1(152) 1(152) 1(152) 0(152)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0) 71(105) 32(135) 22(139) 18(139) 10(140) 6(140) 5(140) 4(140) 4(140) 4(140) 4(140) 3(140) 3(140) 3(140) 3(140) 3(140) 1(140) 1(140) 1(140) 0(141)

NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: General disorders and administration site conditions

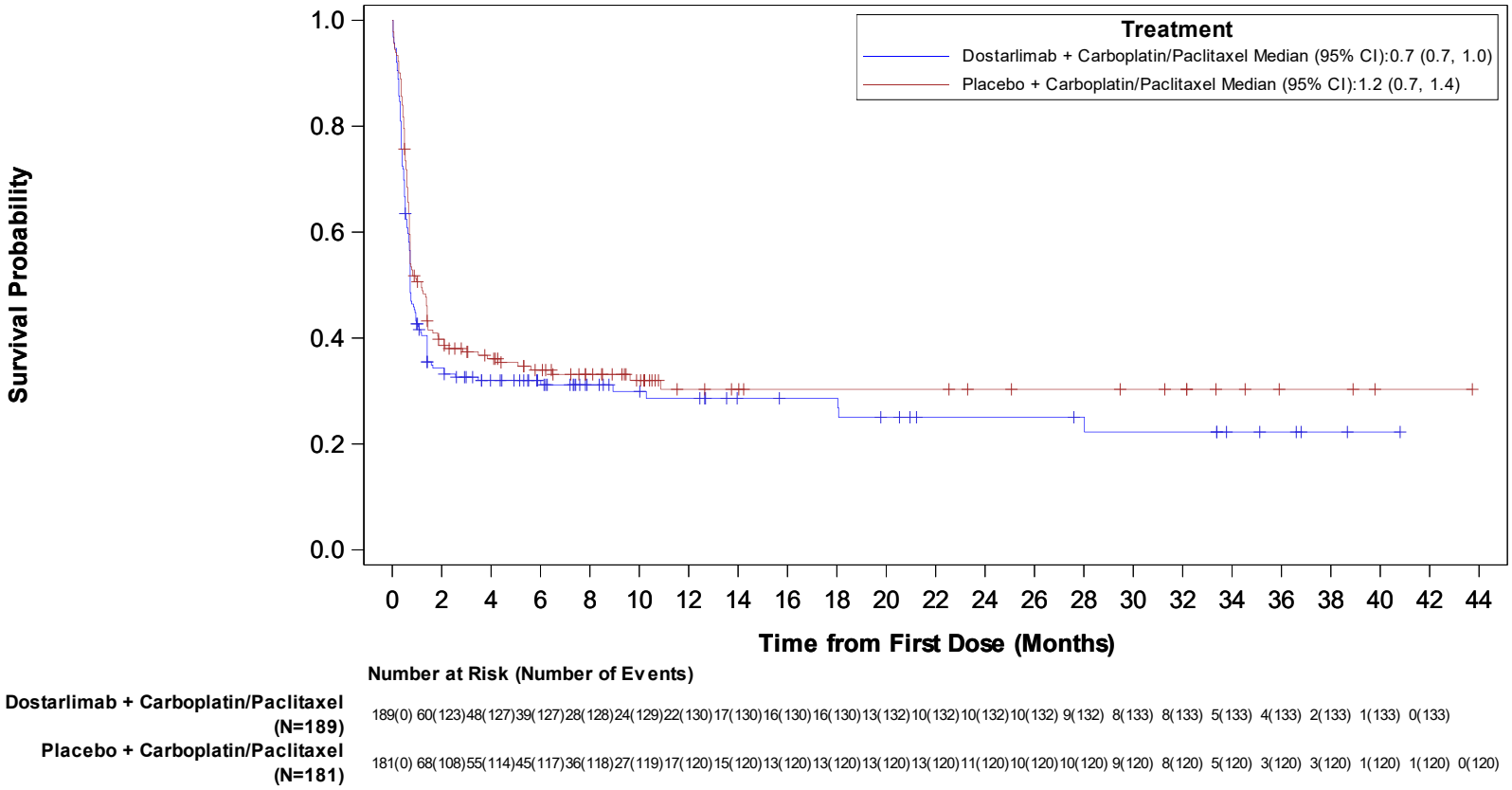


Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	88(99)	60(120)	47(124)	38(126)	27(129)	20(129)	14(129)	12(129)	11(129)	9(129)	8(129)	8(129)	8(129)	7(130)	7(130)	7(130)	5(130)	3(130)	1(130)	0(131)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	77(99)	50(118)	37(125)	30(125)	21(127)	15(128)	14(128)	12(129)	10(130)	9(130)	9(130)	7(131)	7(131)	7(131)	6(131)	4(131)	2(131)	1(131)	0(131)	

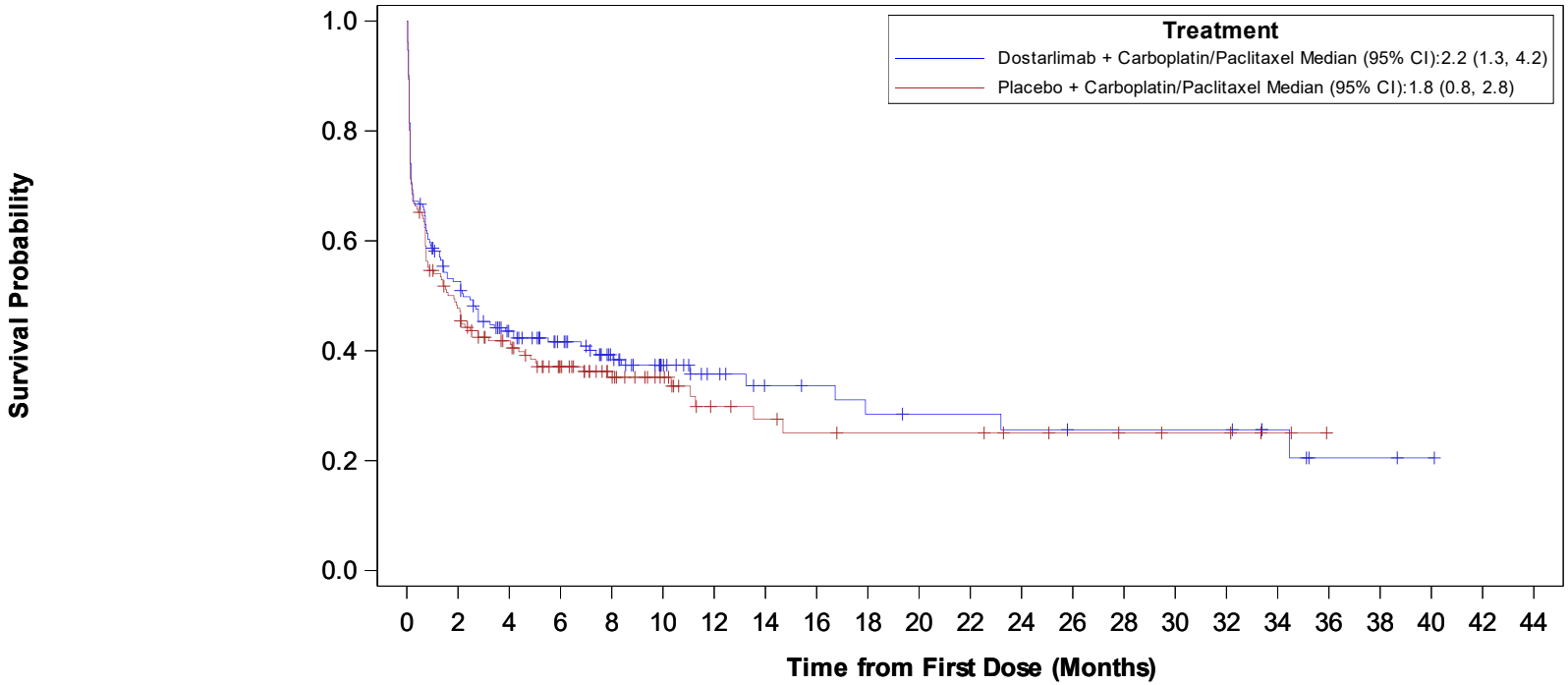
NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Skin and subcutaneous tissue disorders



NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Musculoskeletal and connective tissue disorders



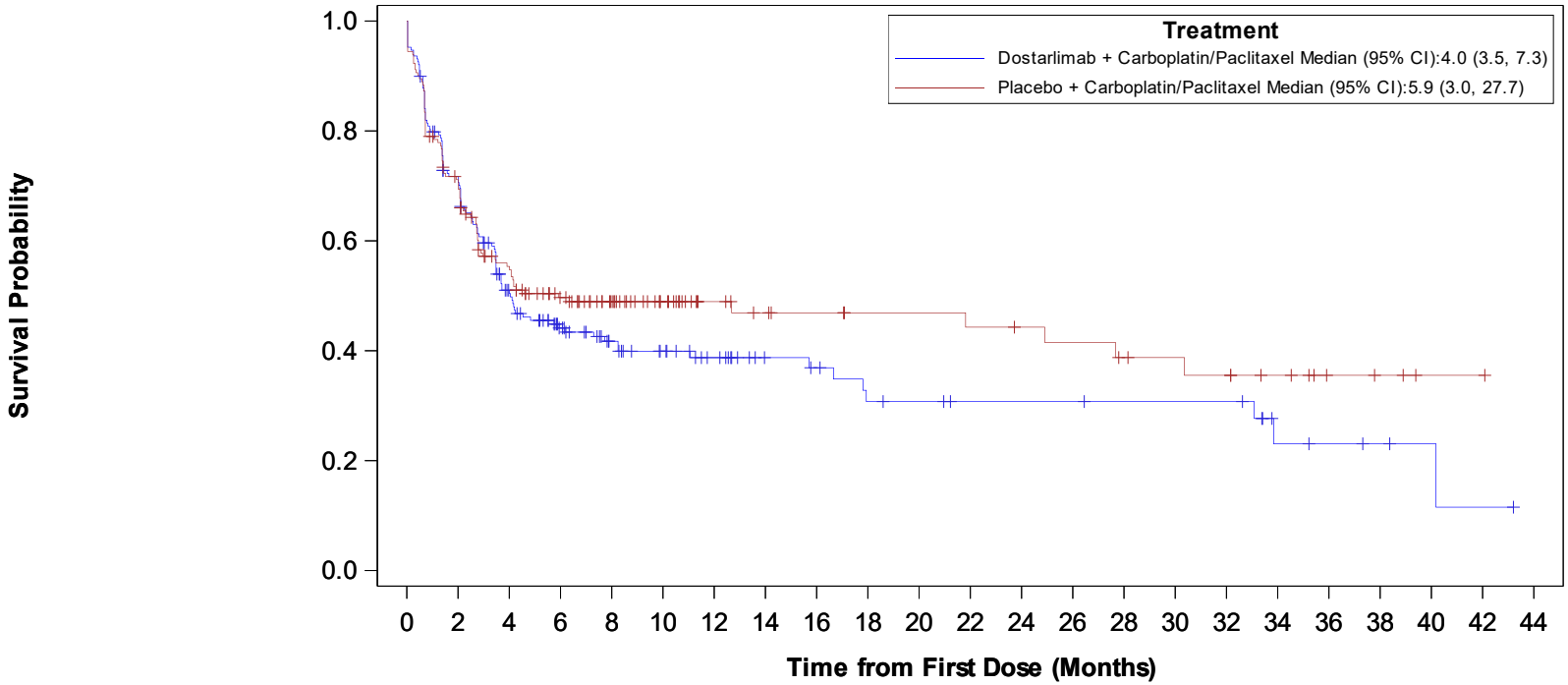
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	95(89)	70(105)	57(108)	43(111)	28(113)	19(114)	14(115)	13(115)	11(117)	10(117)	10(117)	9(118)	8(118)	8(118)	8(118)	8(118)	5(118)	2(119)	2(119)	1(119)	0(119)		
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	83(94)	64(104)	47(111)	33(113)	24(113)	14(116)	12(117)	10(118)	9(118)	9(118)	9(118)	7(118)	6(118)	5(118)	4(118)	4(118)	2(118)	0(118)					

NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations

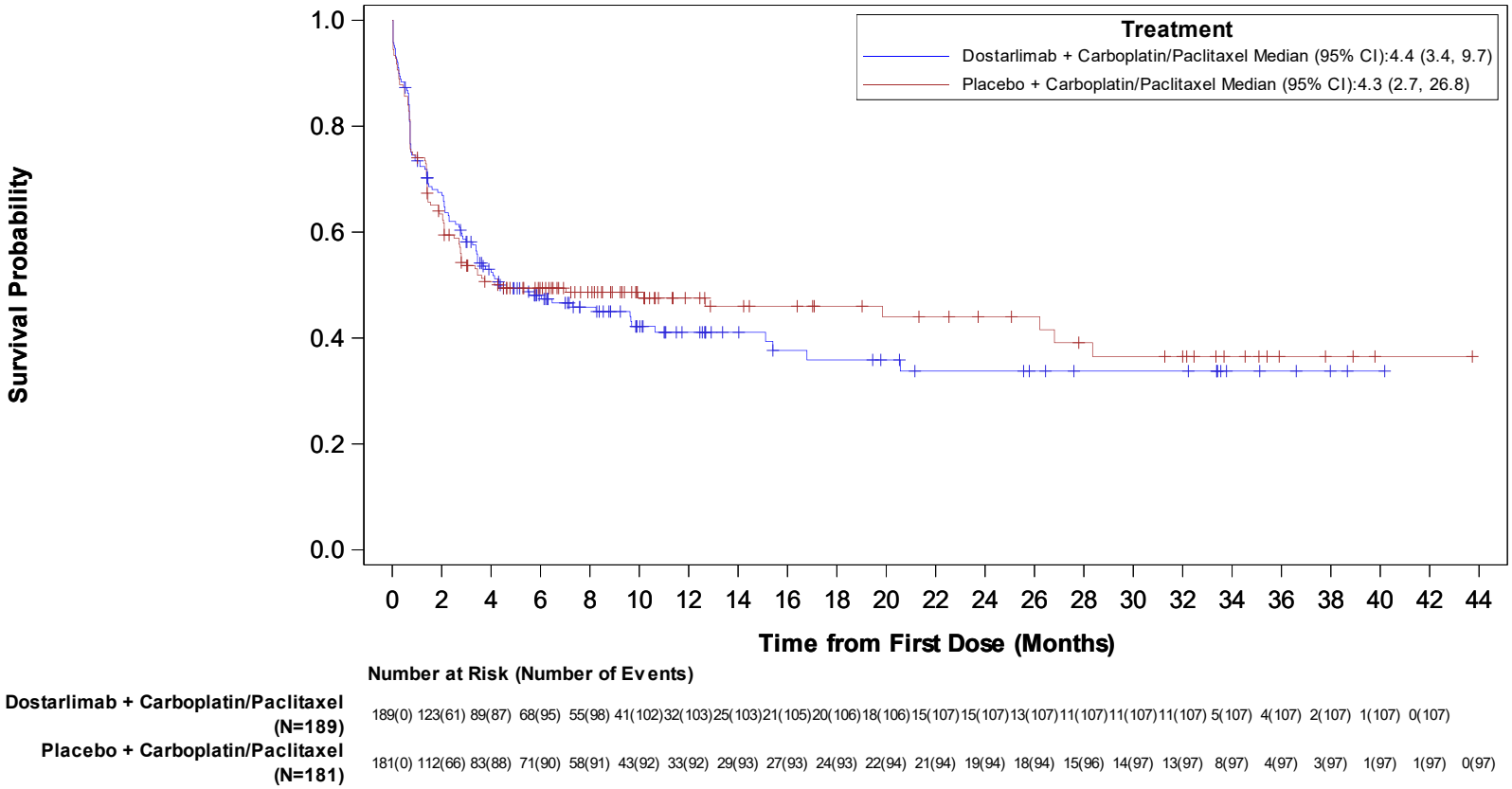


Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	131(53)	84(90)	61(101)	46(104)	38(106)	30(107)	21(107)	19(108)	15(111)	14(111)	12(111)	12(111)	12(111)	11(111)	11(111)	11(111)	5(113)	4(113)	3(113)	2(113)	1(114)	0(114)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	125(52)	90(79)	68(88)	53(89)	38(89)	26(89)	22(90)	20(90)	18(90)	18(90)	17(91)	16(91)	15(92)	13(93)	12(93)	11(94)	8(94)	4(94)	3(94)	1(94)	1(94)	0(94)	

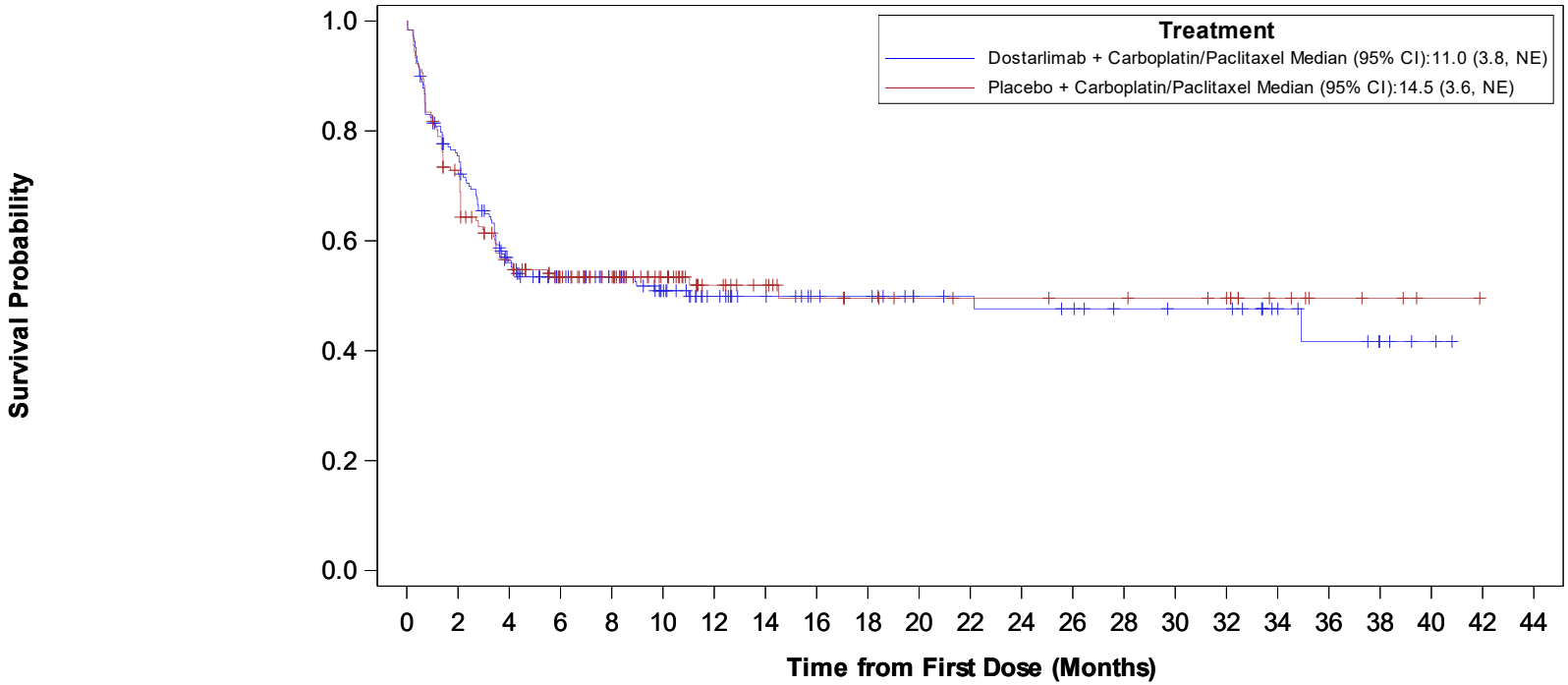
NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Metabolism and nutrition disorders



NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Blood and lymphatic system disorders

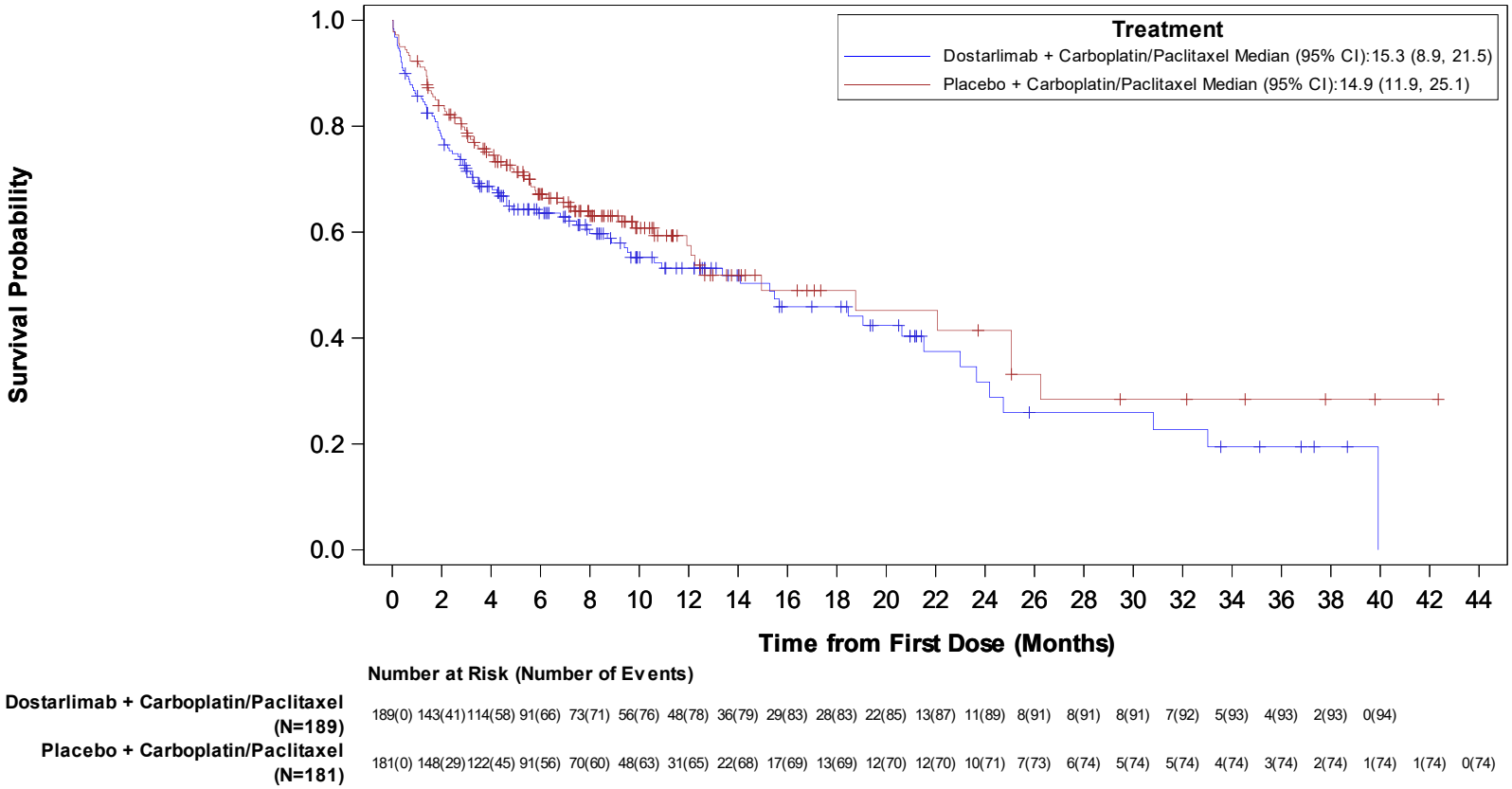


Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	137(46)	96(80)	78(85)	68(85)	55(88)	42(89)	35(89)	30(89)	29(89)	23(89)	22(89)	21(90)	20(90)	17(90)	16(90)	16(90)	10(90)	7(91)	4(91)	2(91)	0(91)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	128(49)	92(78)	75(82)	64(82)	47(82)	31(83)	26(83)	21(84)	19(84)	17(84)	16(84)	16(84)	15(84)	15(84)	14(84)	13(84)	7(84)	4(84)	3(84)	1(84)	0(84)

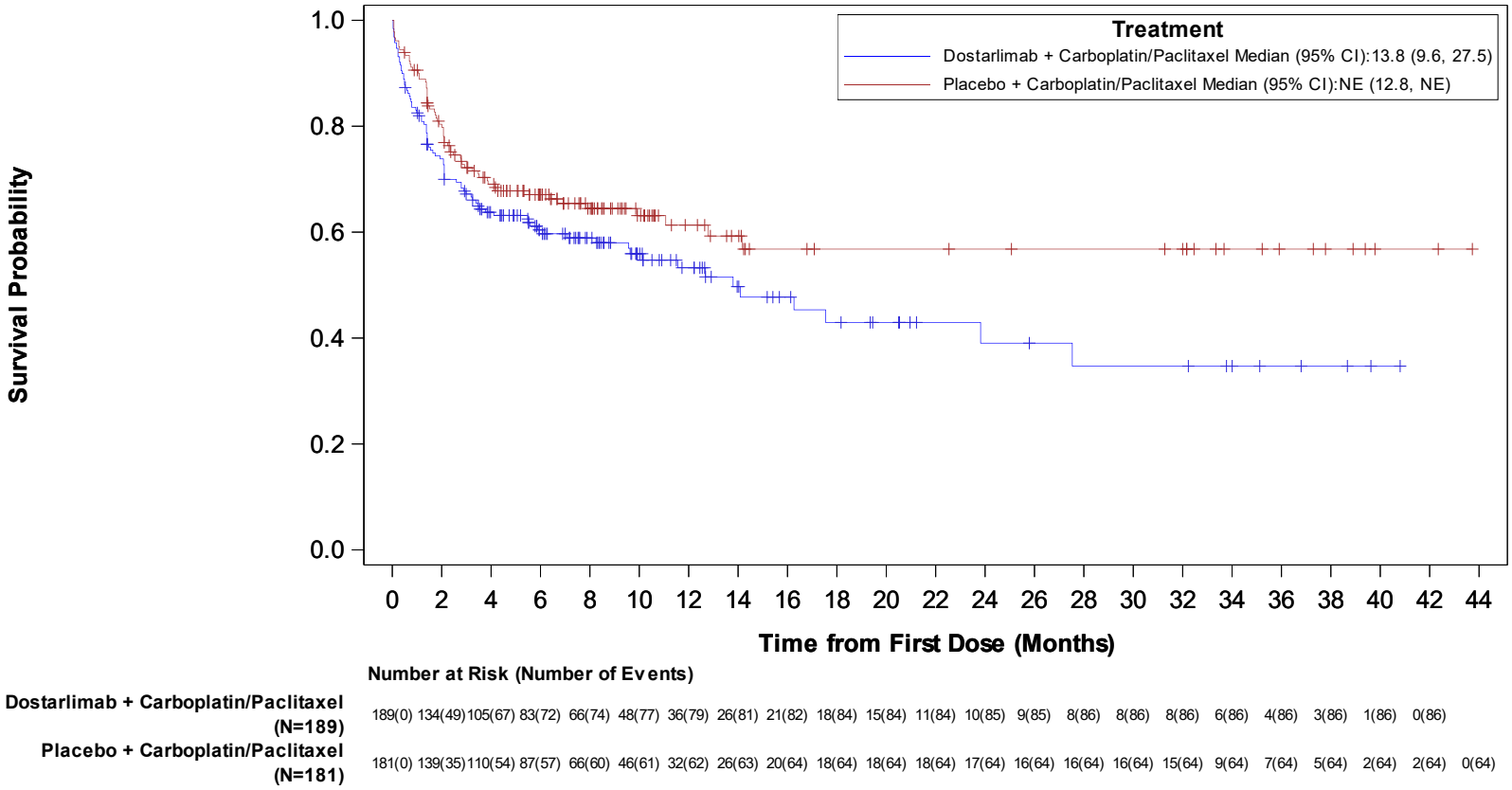
NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Infections and infestations



NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

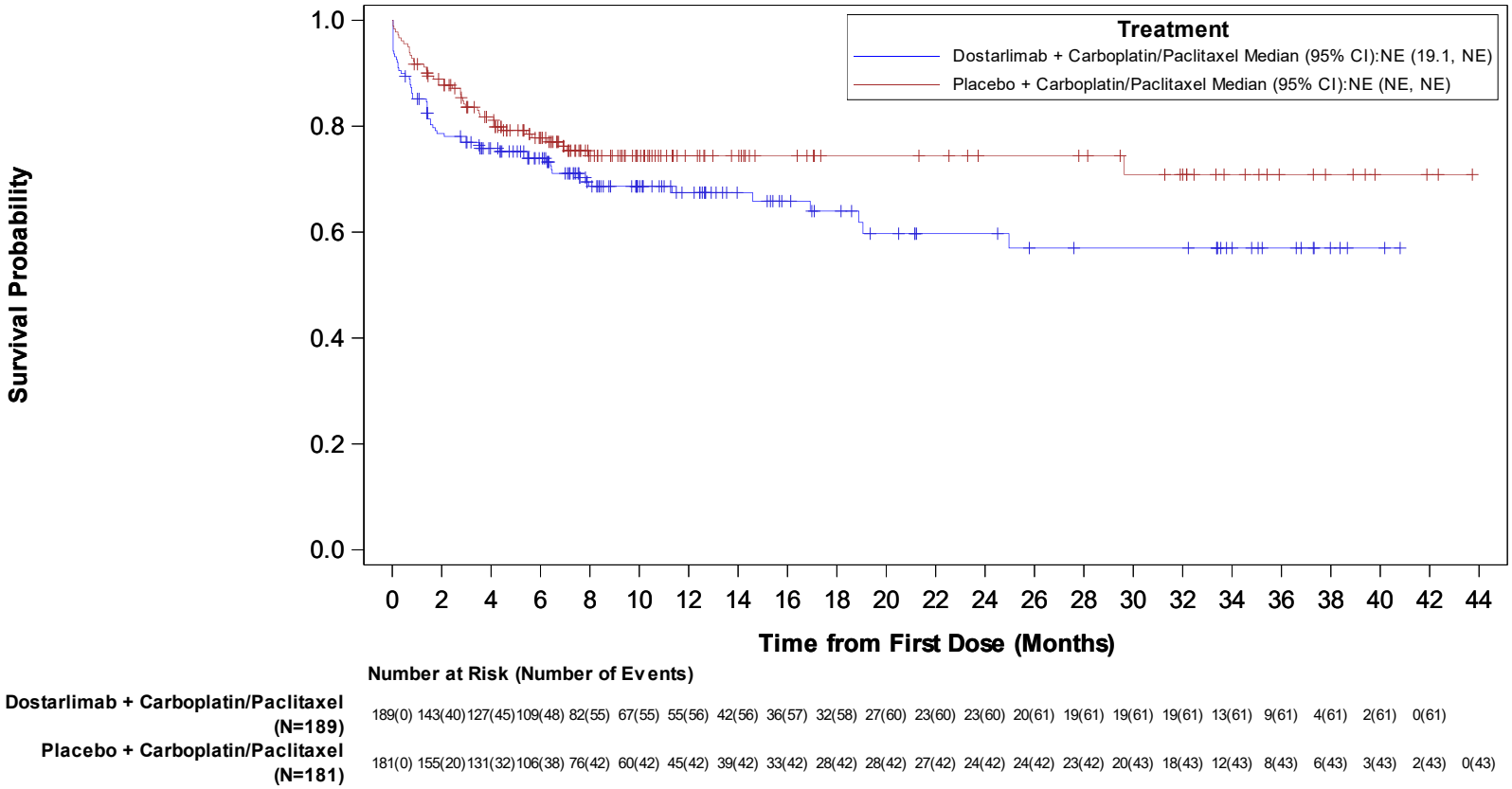
Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Respiratory, thoracic and mediastinal disorders



NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects

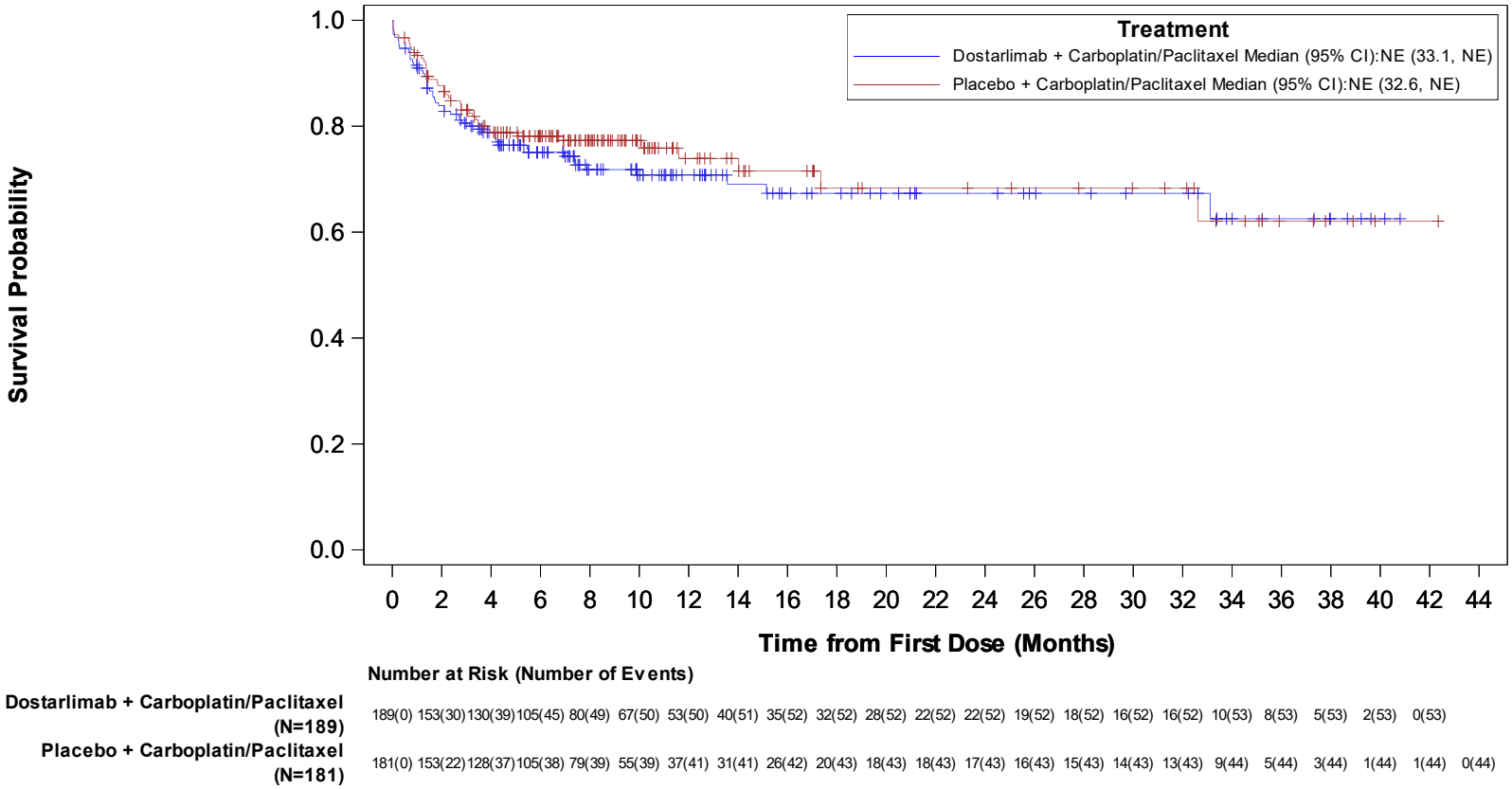
System Organ Class: Psychiatric disorders



NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

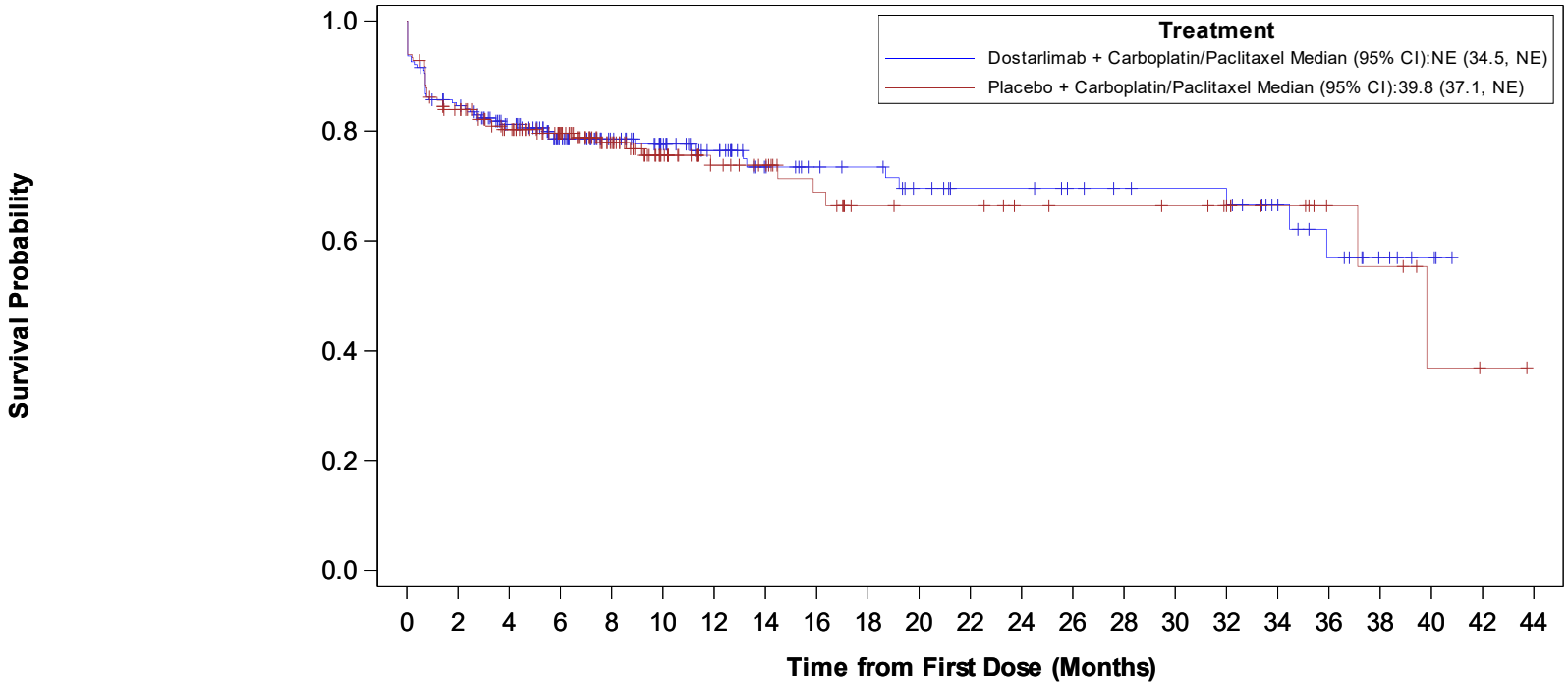
Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders



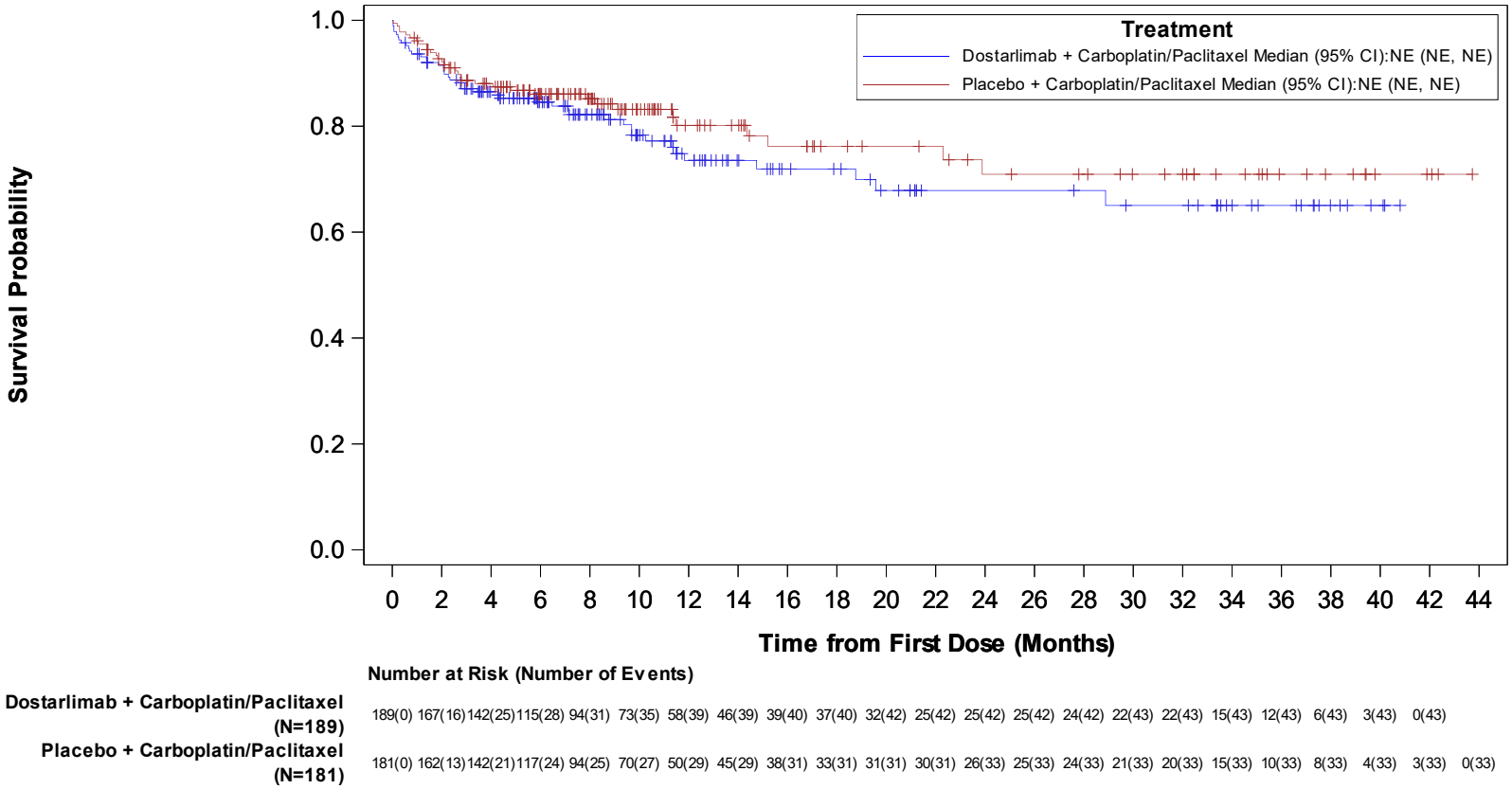
NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Injury, poisoning and procedural complications



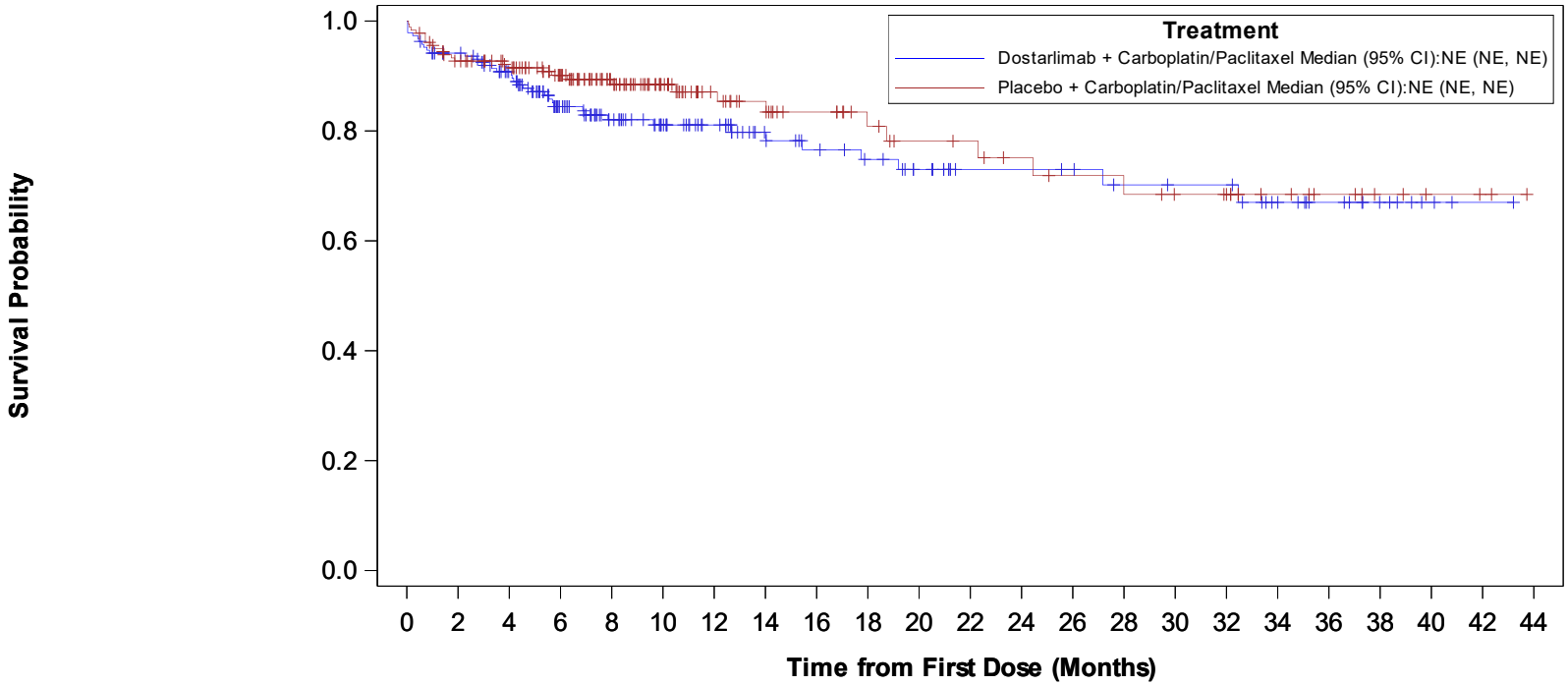
NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Renal and urinary disorders



NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

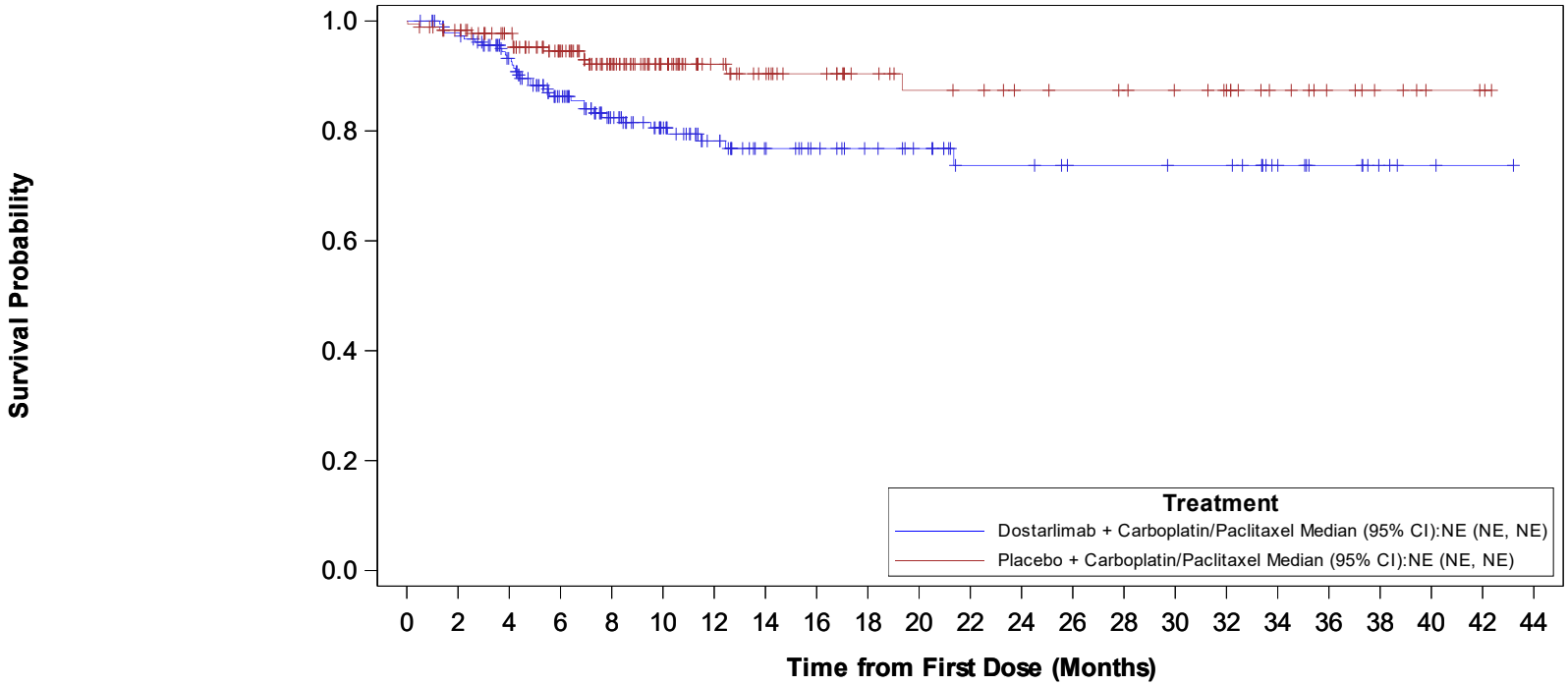
Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Reproductive system and breast disorders



NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders



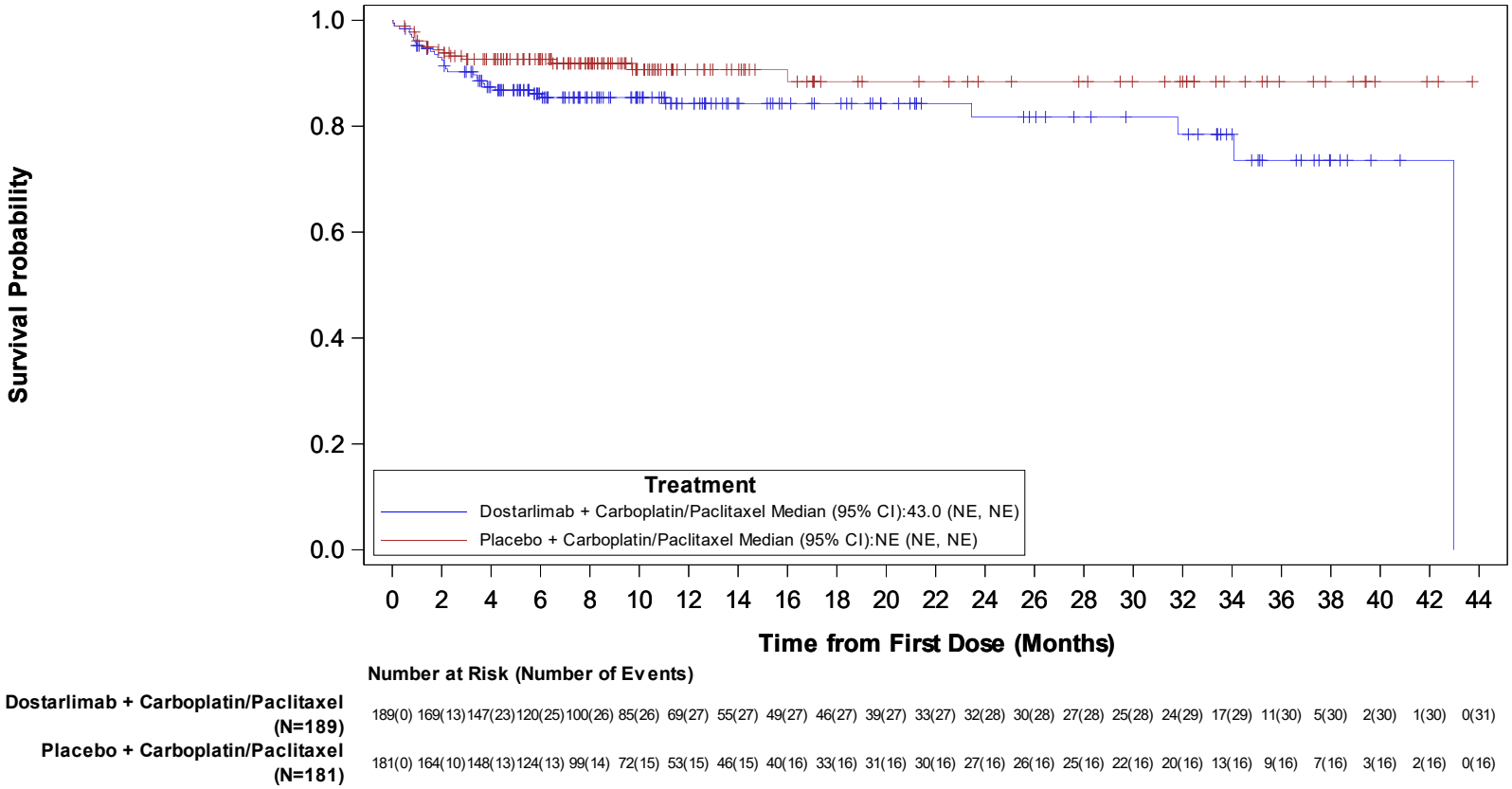
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	178(4)	154(12)	122(23)	95(28)	76(30)	59(32)	46(33)	40(33)	35(33)	31(33)	23(34)	23(34)	20(34)	20(34)	19(34)	19(34)	12(34)	8(34)	4(34)	2(34)	1(34)	0(34)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	171(3)	157(4)	130(9)	100(12)	75(12)	55(12)	46(13)	40(13)	33(13)	29(14)	28(14)	25(14)	24(14)	23(14)	21(14)	19(14)	13(14)	9(14)	6(14)	3(14)	2(14)	0(14)

NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects

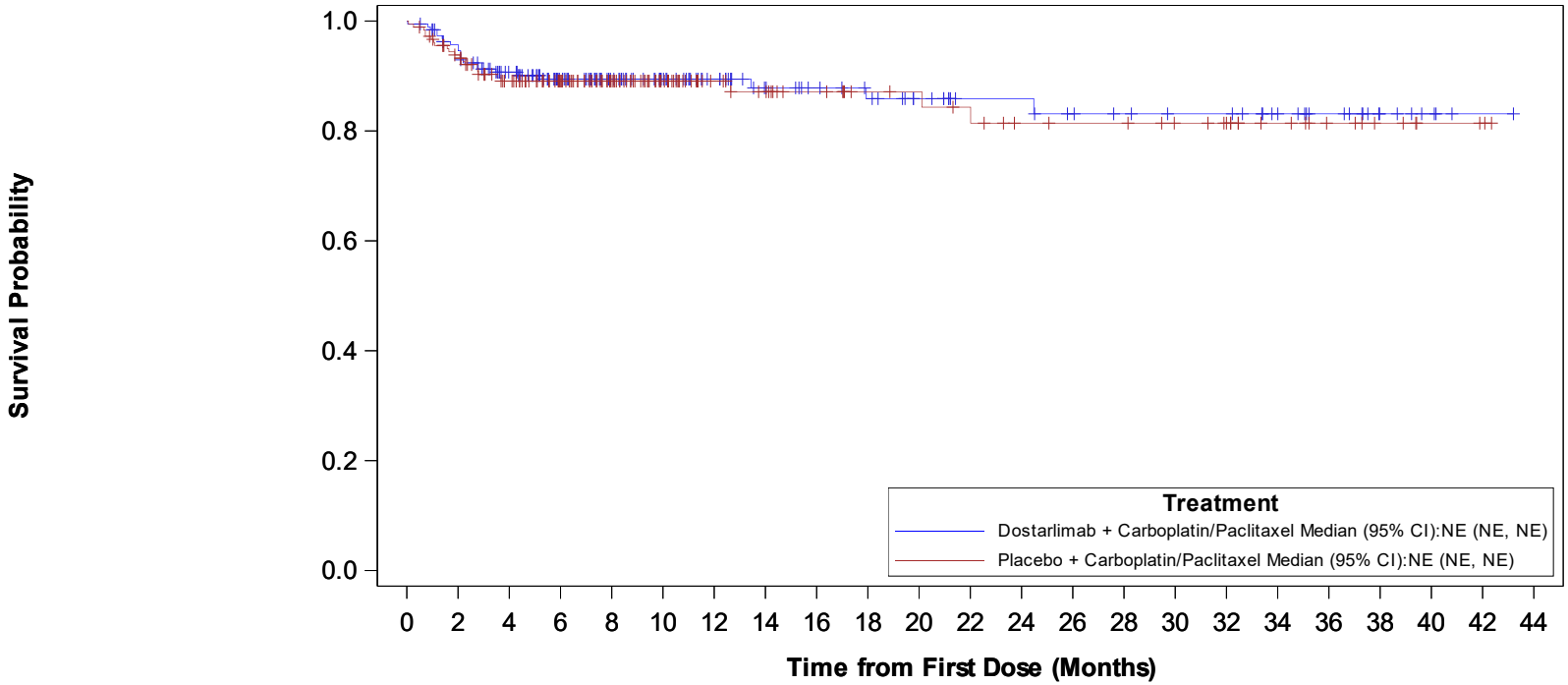
System Organ Class: Cardiac disorders



NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Eye disorders



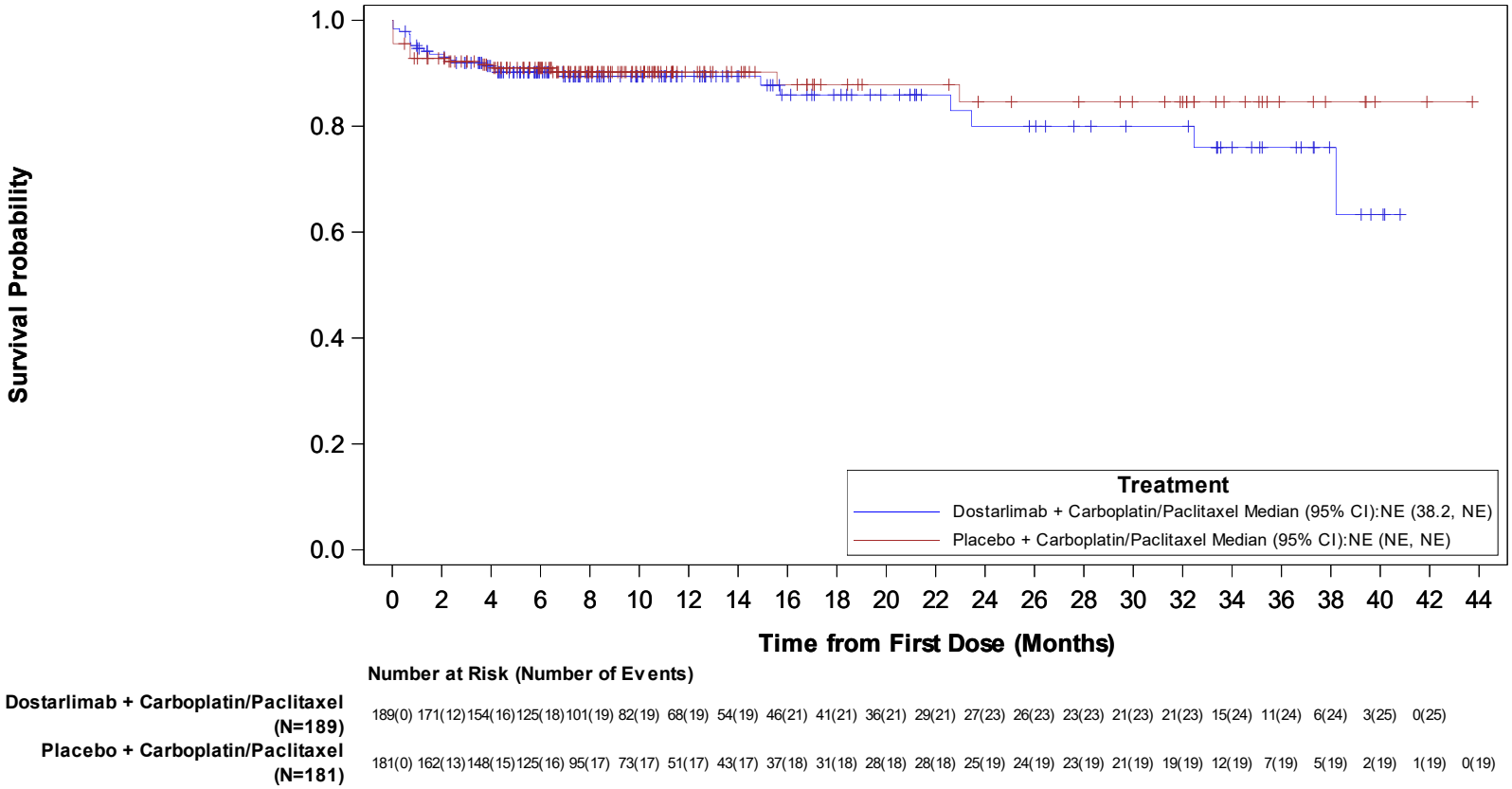
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	174(8)	151(17)	121(19)	97(19)	79(19)	65(19)	53(20)	48(20)	44(21)	38(21)	31(21)	31(21)	28(22)	26(22)	24(22)	24(22)	19(22)	14(22)	7(22)	4(22)	1(22)	0(22)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	163(11)	142(19)	117(19)	93(19)	69(19)	48(19)	43(20)	37(20)	32(20)	31(20)	29(21)	25(22)	24(22)	24(22)	21(22)	19(22)	13(22)	9(22)	6(22)	3(22)	2(22)	0(22)

NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Immune system disorders



NE = Not Estimable.
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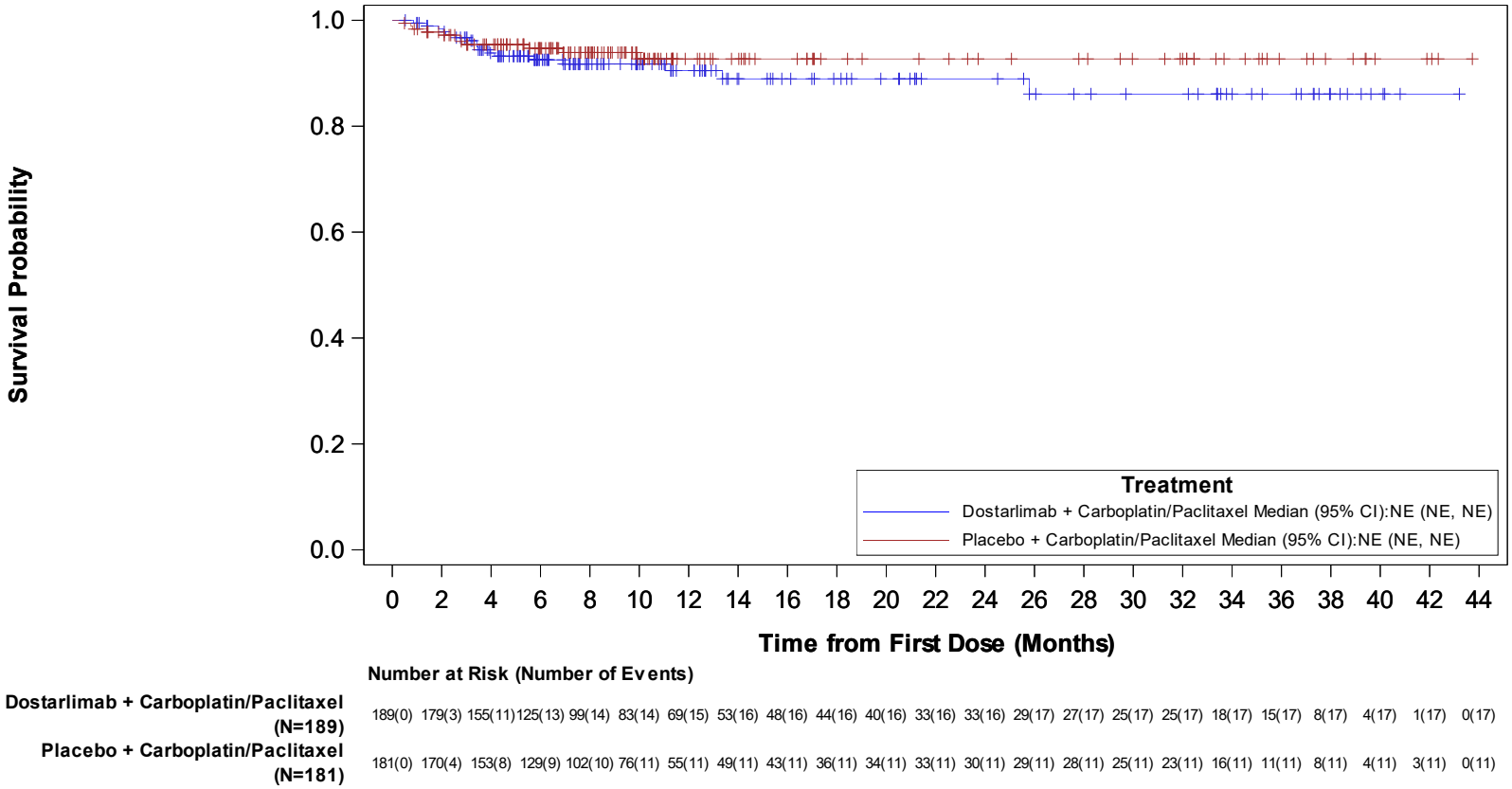
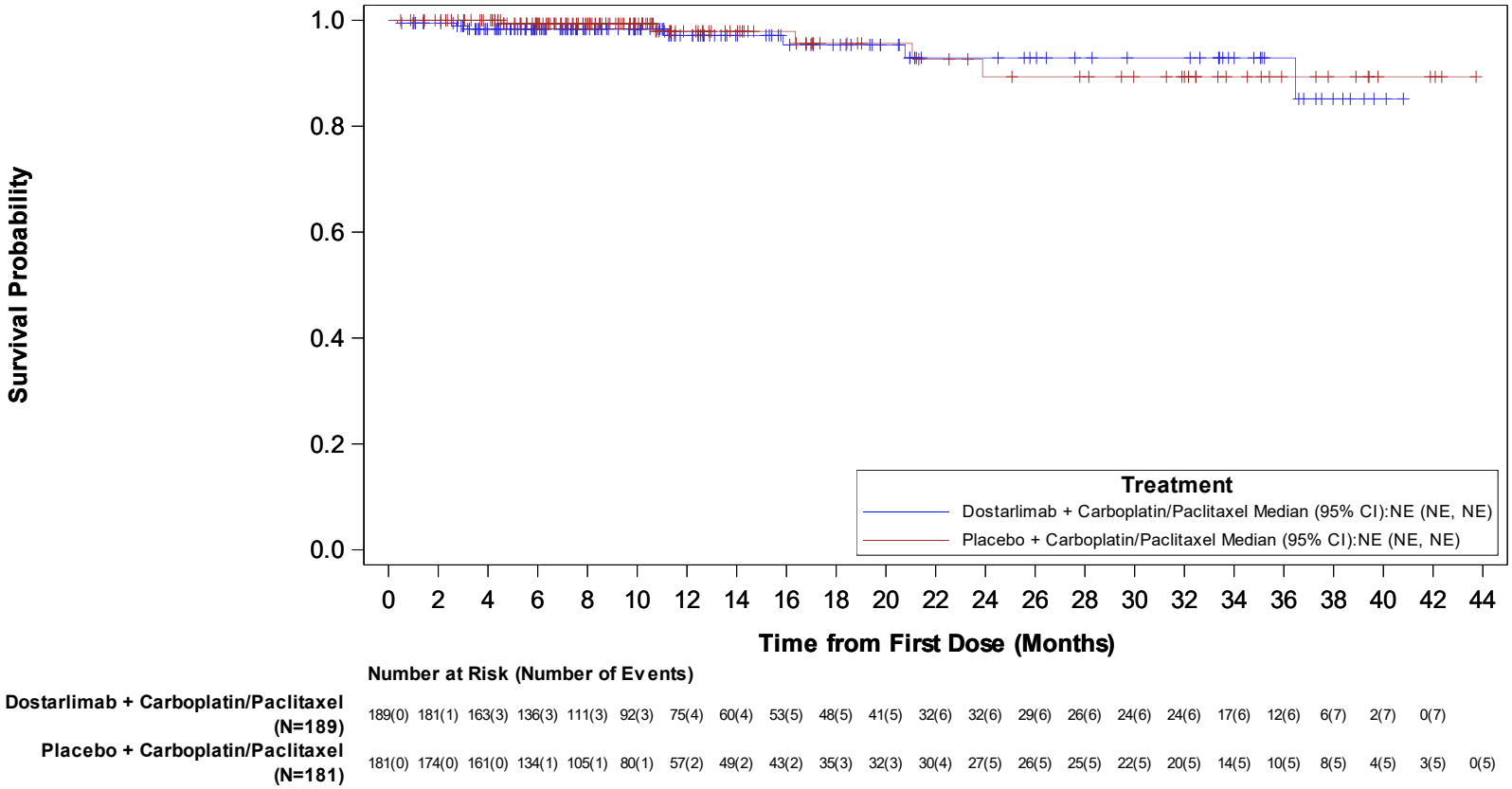
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Ear and labyrinth disorders



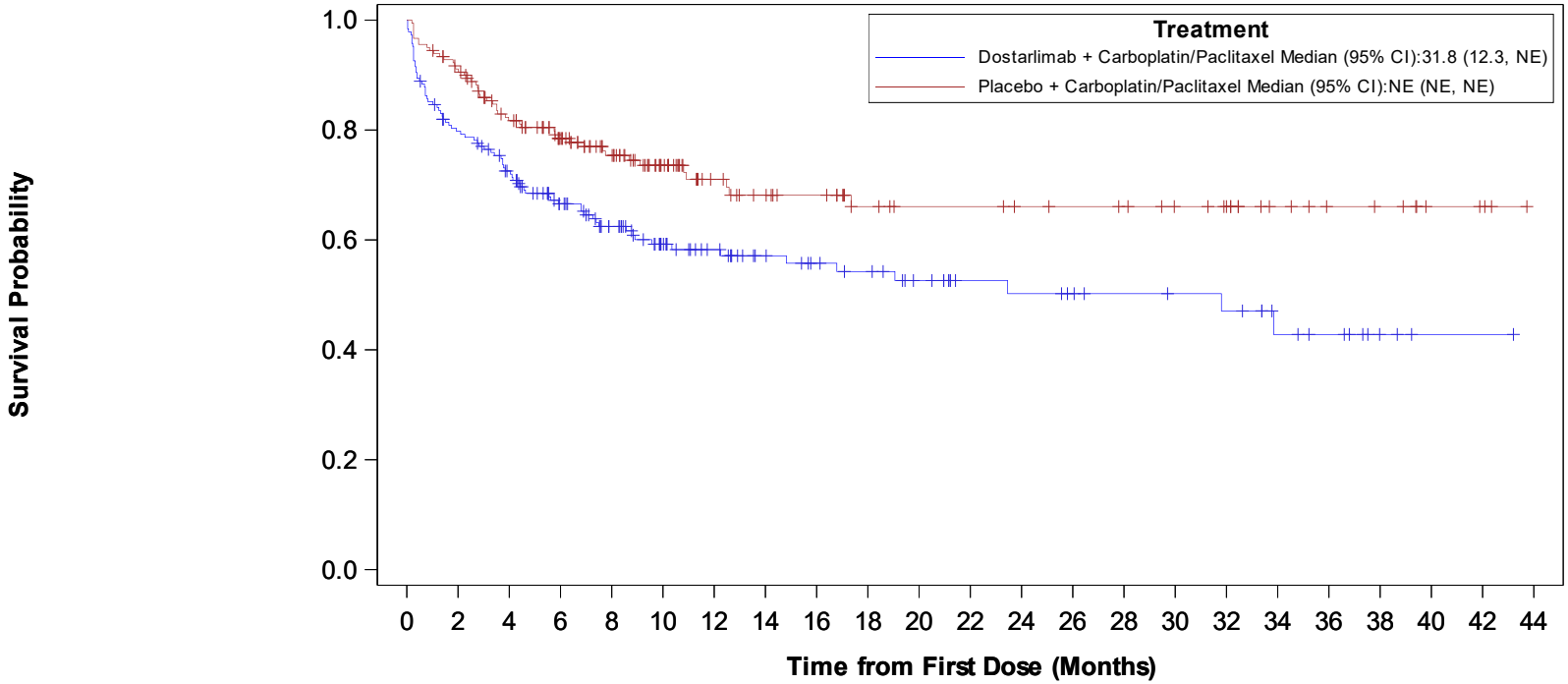
NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.0902 Kaplan Meier Plot of Time to Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Neoplasms benign, malignant and unspecified (incl cysts and polyps)



NE = Not Estimable.
Program: f_3_0902_km_ttae_soc.sas, Output: f_3_0902_km_ttae_soc.rtf, Generated on: 20SEP2024 11:39,
Data Cutoff Date: 22SEP2023

Figure 3.1302 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Serious Adverse Events
(Safety Analysis Set): MMRp/MSS Subjects

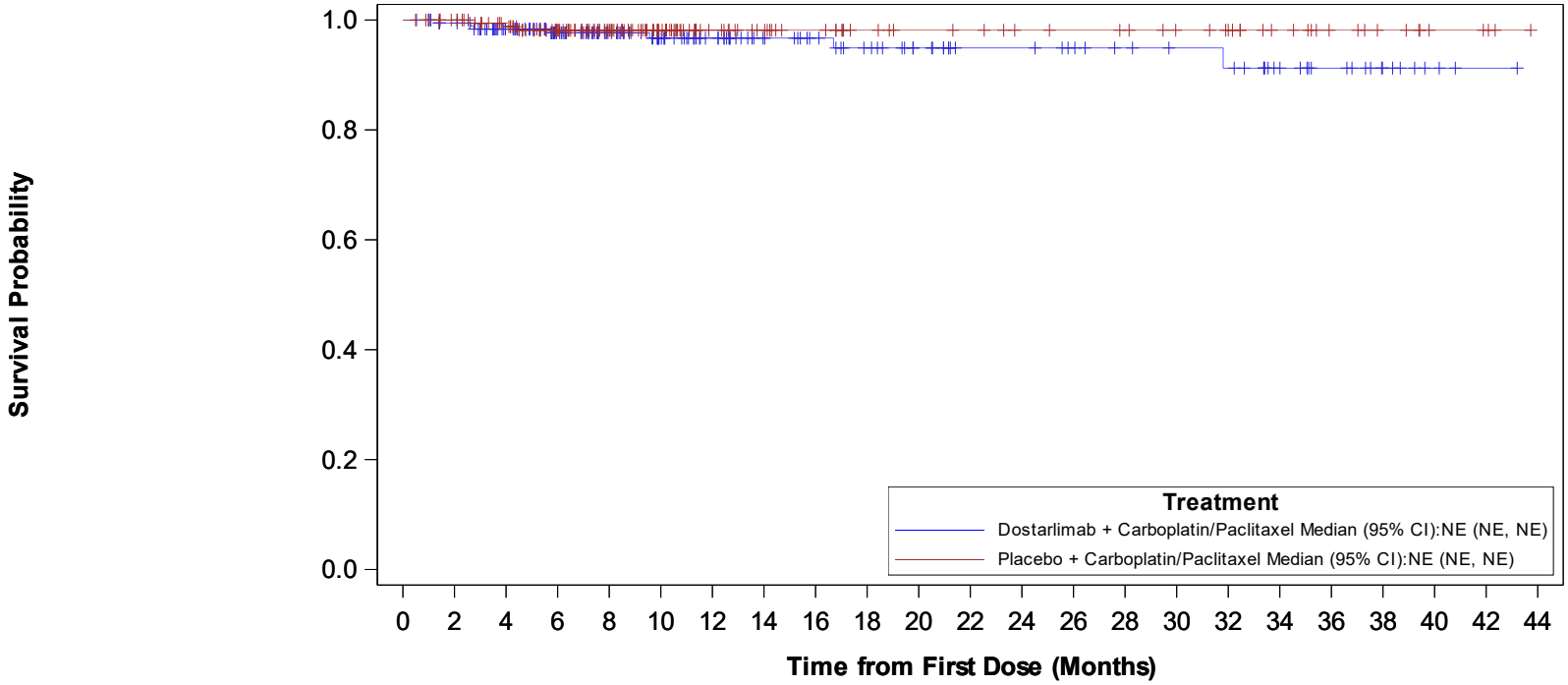


Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	146(38)	127(51)	102(61)	84(67)	64(71)	53(72)	43(73)	38(74)	35(75)	29(76)	22(76)	21(77)	19(77)	17(77)	16(77)	15(78)	10(79)	8(79)	3(79)	1(79)	1(79)	0(79)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	161(16)	135(32)	113(37)	93(41)	69(43)	50(45)	43(47)	39(47)	31(48)	28(48)	28(48)	26(48)	25(48)	24(48)	21(48)	19(48)	12(48)	9(48)	8(48)	4(48)	3(48)	0(48)

NE = Not Estimable.
Program: f_3_1302_km_sae.sas, Output: f_3_1302_km_sae.rtf, Generated on: 20SEP2024 10:23,
Data Cutoff Date: 22SEP2023

Figure 3.1702 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Respiratory, thoracic and mediastinal disorders
Preferred Term: Pulmonary embolism



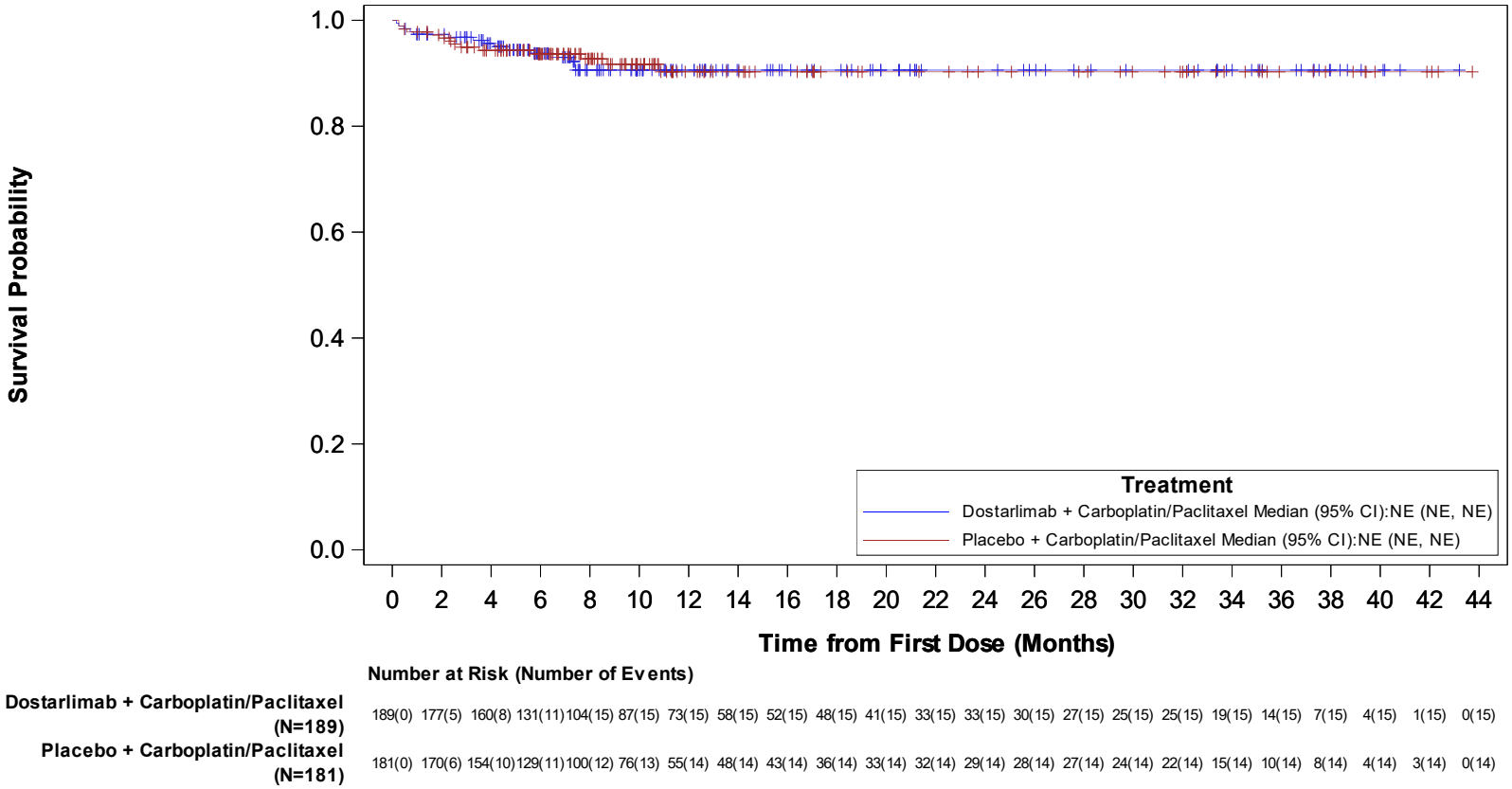
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	181(1)	162(3)	134(4)	111(4)	91(5)	76(5)	61(5)	55(5)	49(6)	42(6)	34(6)	34(6)	31(6)	28(6)	26(6)	25(7)	18(7)	13(7)	7(7)	3(7)	1(7)	0(7)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	174(0)	159(2)	134(3)	106(3)	80(3)	58(3)	50(3)	44(3)	37(3)	34(3)	33(3)	30(3)	29(3)	28(3)	25(3)	23(3)	16(3)	11(3)	8(3)	4(3)	3(3)	0(3)

Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_1702_km_sae_socpt.sas, Output: f_3_1702_km_sae_socpt.rtf, Generated on: 19SEP2024 15:44,
Data Cutoff Date: 22SEP2023

Figure 3.2102 Graph of Kaplan Meier Plot of Time to Treatment-Emergent Serious Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

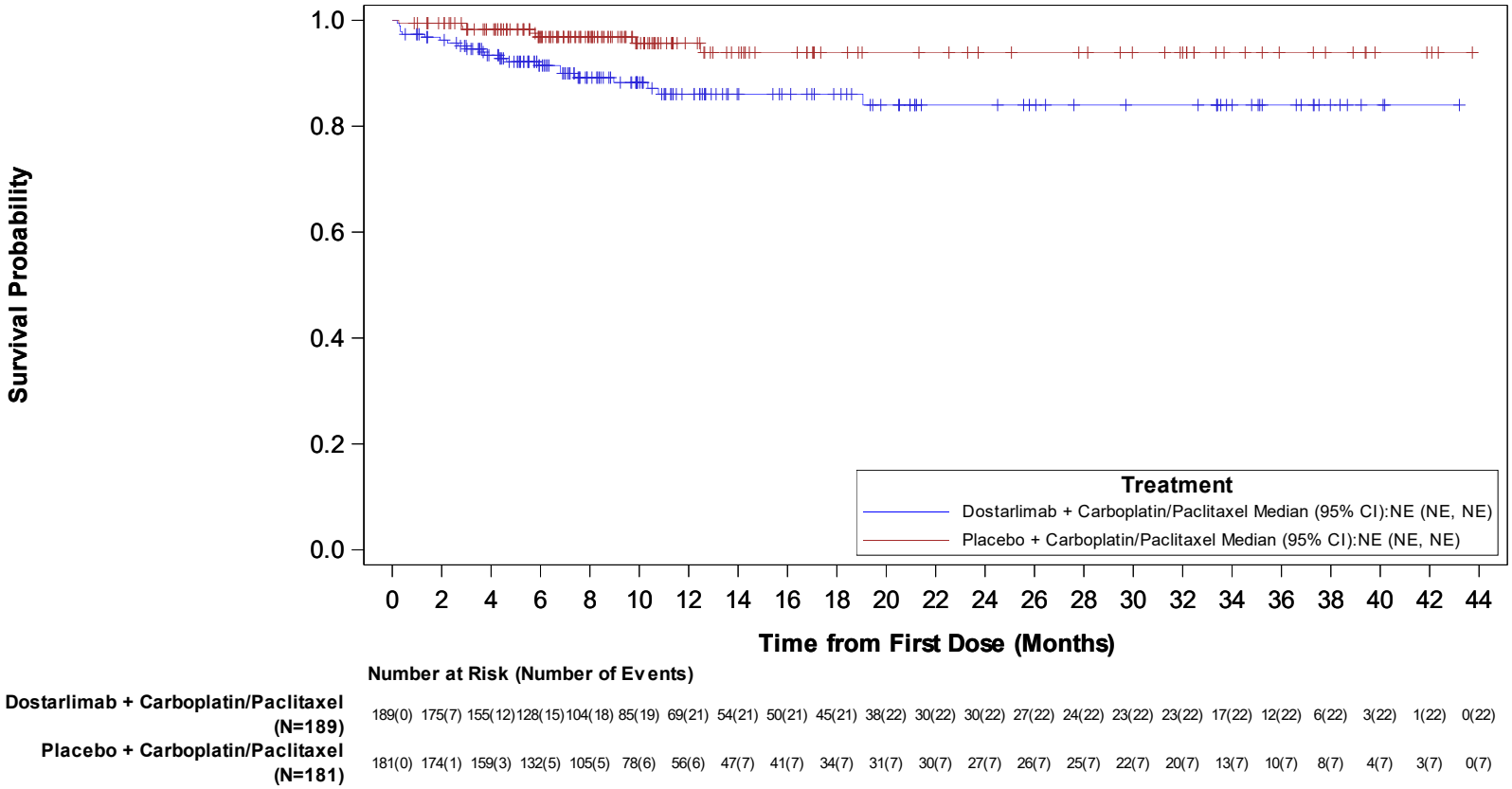
System Organ Class: Gastrointestinal disorders



NE = Not Estimable.
Program: f_3_2102_km_ser_soc.sas, Output: f_3_2102_km_ser_soc.rtf, Generated on: 20SEP2024 08:21,
Data Cutoff Date: 22SEP2023

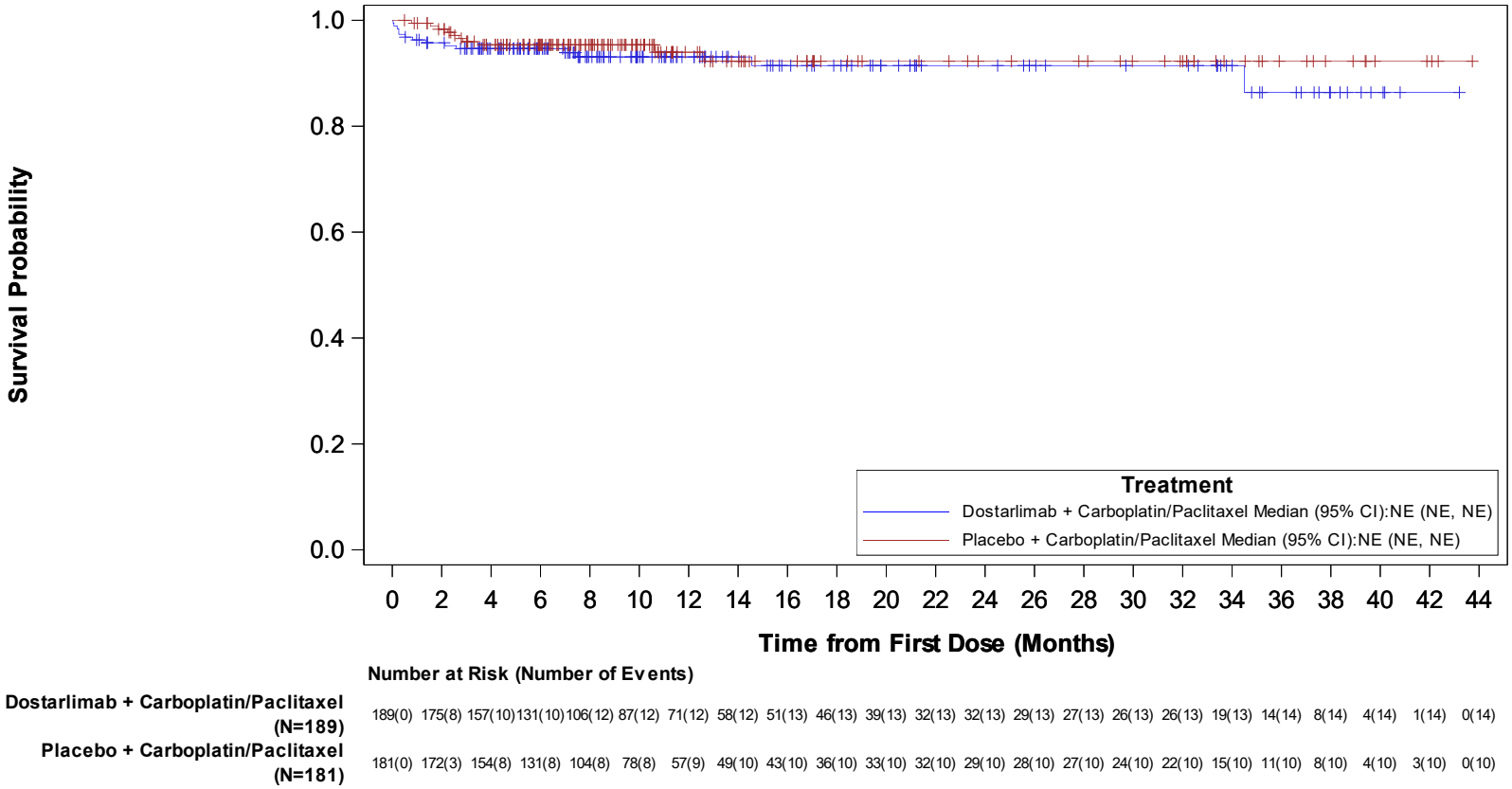
Figure 3.2102 Graph of Kaplan Meier Plot of Time to Treatment-Emergent Serious Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations



NE = Not Estimable.
Program: f_3_2102_km_ser_soc.sas, Output: f_3_2102_km_ser_soc.rtf, Generated on: 20SEP2024 08:21,
Data Cutoff Date: 22SEP2023

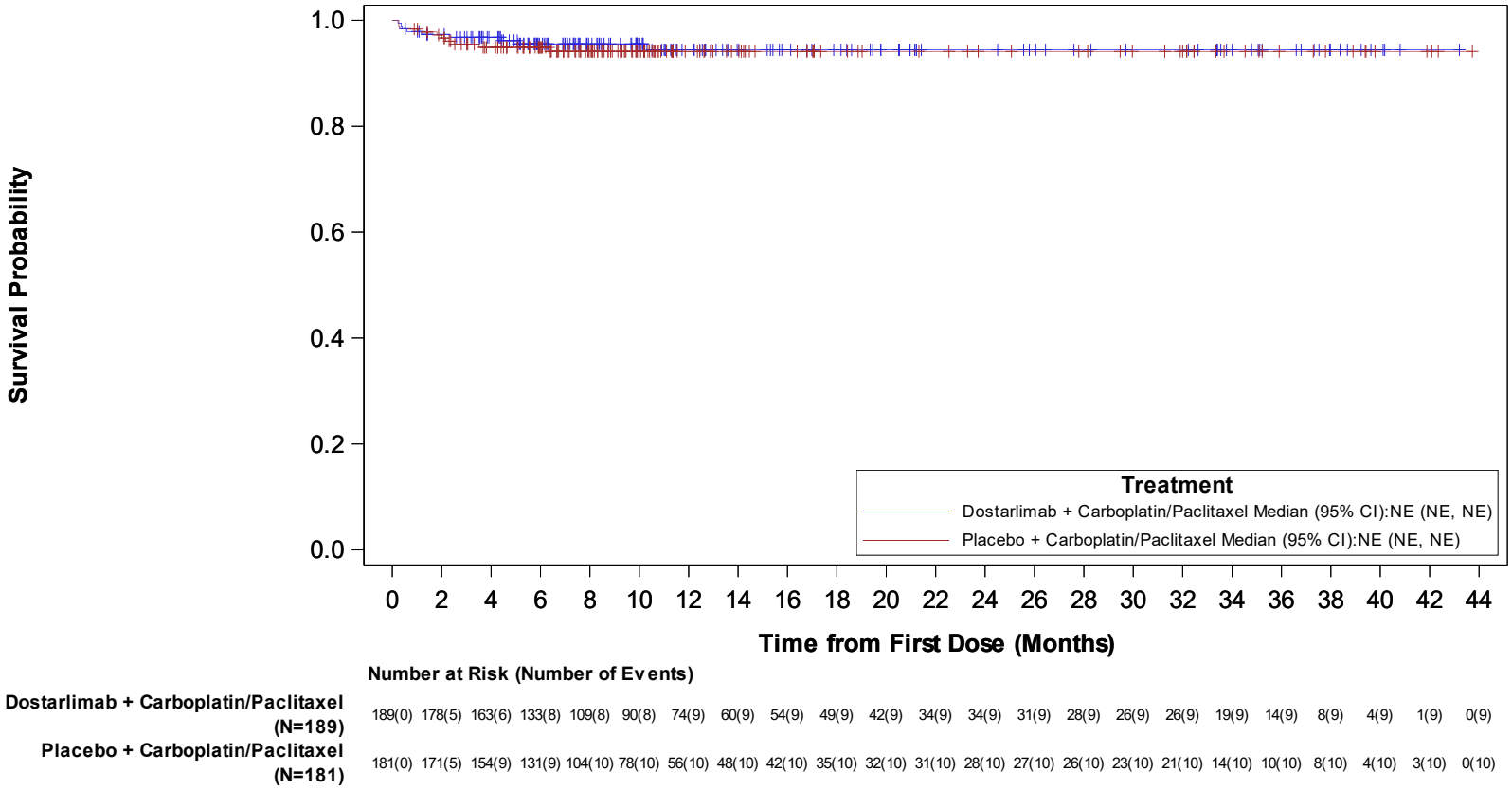
Figure 3.2102 Graph of Kaplan Meier Plot of Time to Treatment-Emergent Serious Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: General disorders and administration site conditions



NE = Not Estimable.
Program: f_3_2102_km_ser_soc.sas, Output: f_3_2102_km_ser_soc.rtf, Generated on: 20SEP2024 08:21,
Data Cutoff Date: 22SEP2023

Figure 3.2102 Graph of Kaplan Meier Plot of Time to Treatment-Emergent Serious Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Blood and lymphatic system disorders

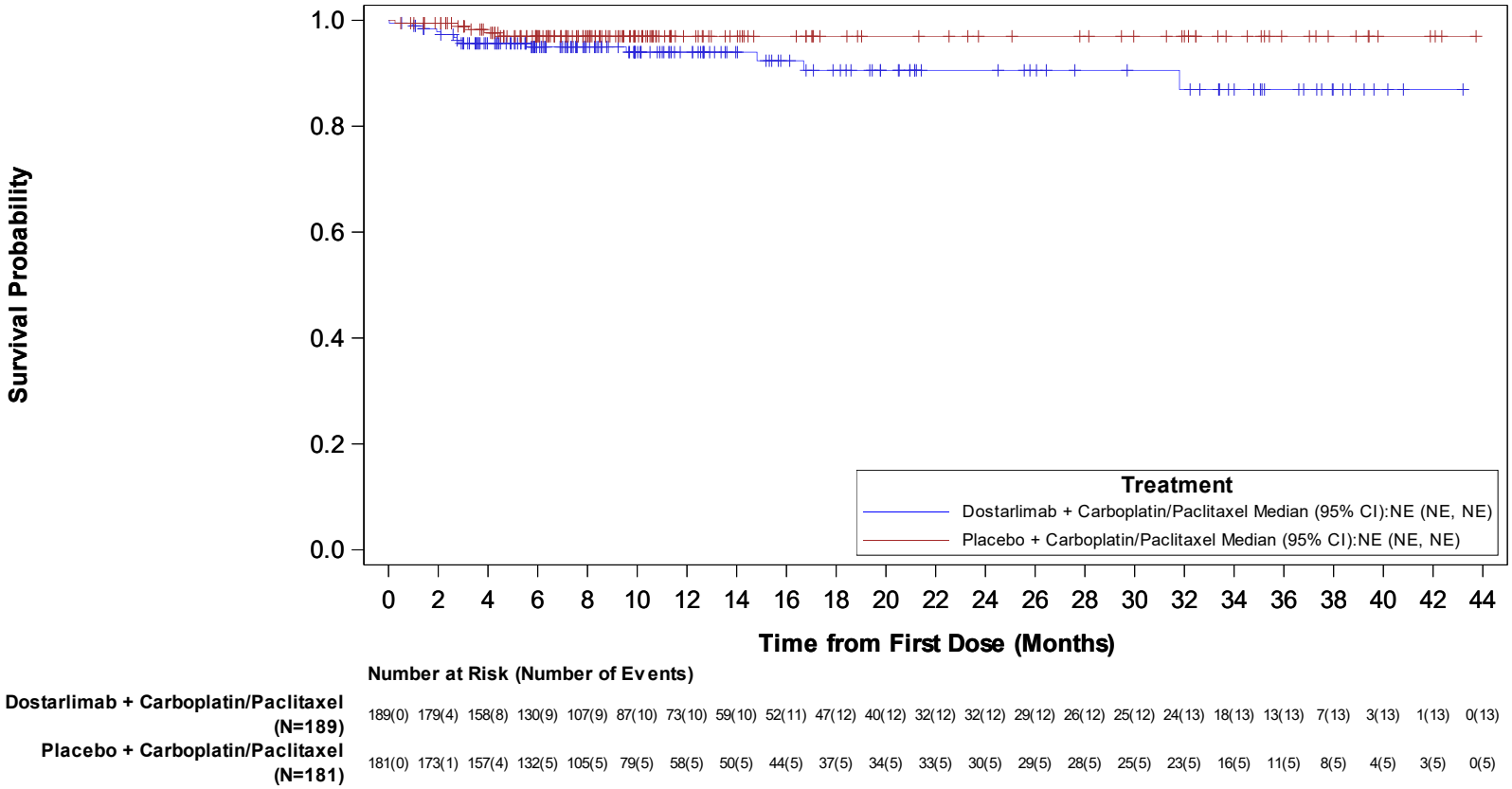


NE = Not Estimable.

Program: f_3_2102_km_ser_soc.sas, Output: f_3_2102_km_ser_soc.rtf, Generated on: 20SEP2024 08:21,

Data Cutoff Date: 22SEP2023

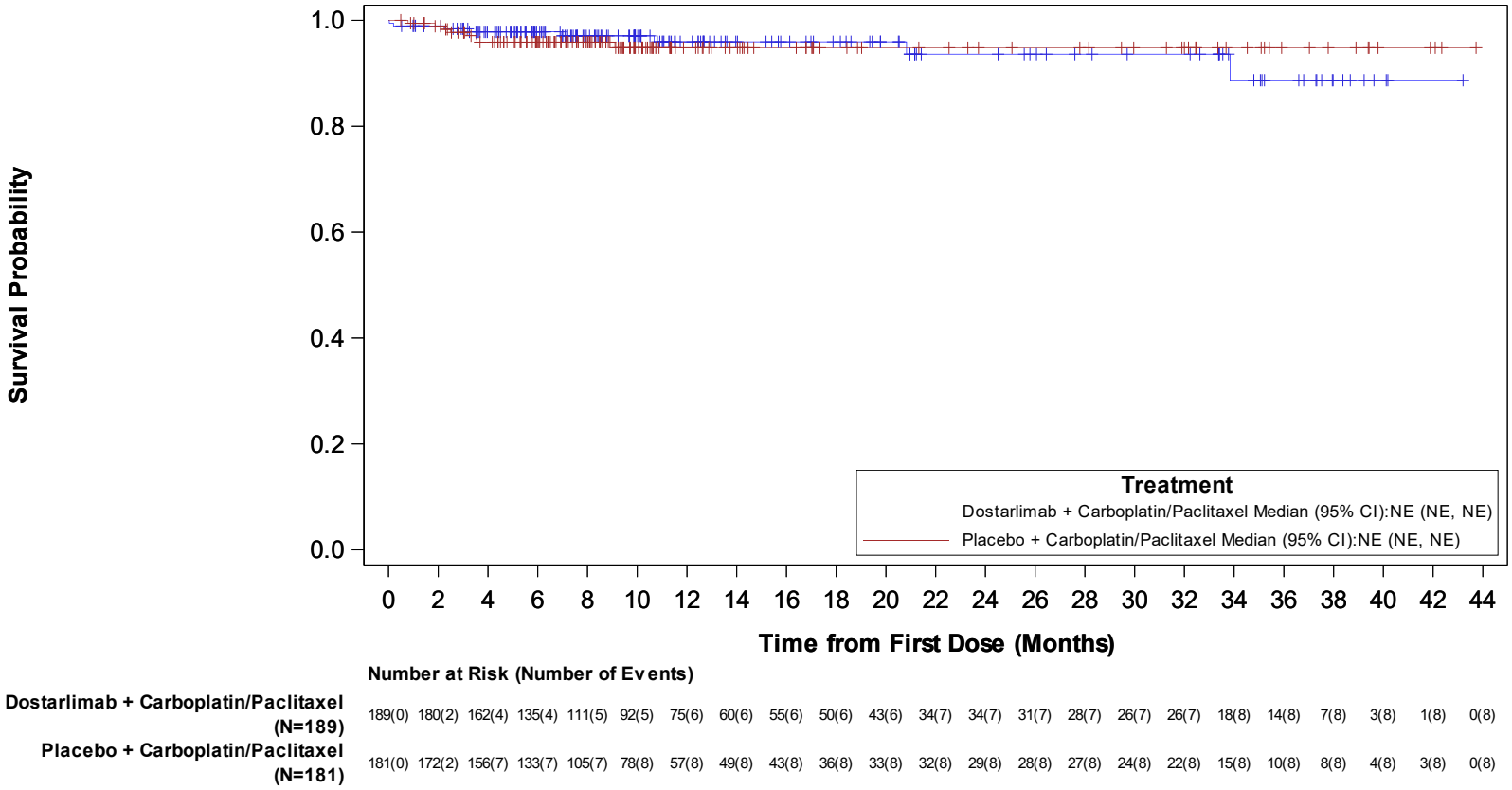
Figure 3.2102 Graph of Kaplan Meier Plot of Time to Treatment-Emergent Serious Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: Respiratory, thoracic and mediastinal disorders



NE = Not Estimable.
Program: f_3_2102_km_ser_soc.sas, Output: f_3_2102_km_ser_soc.rtf, Generated on: 20SEP2024 08:21,
Data Cutoff Date: 22SEP2023

Figure 3.2102 Graph of Kaplan Meier Plot of Time to Treatment-Emergent Serious Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

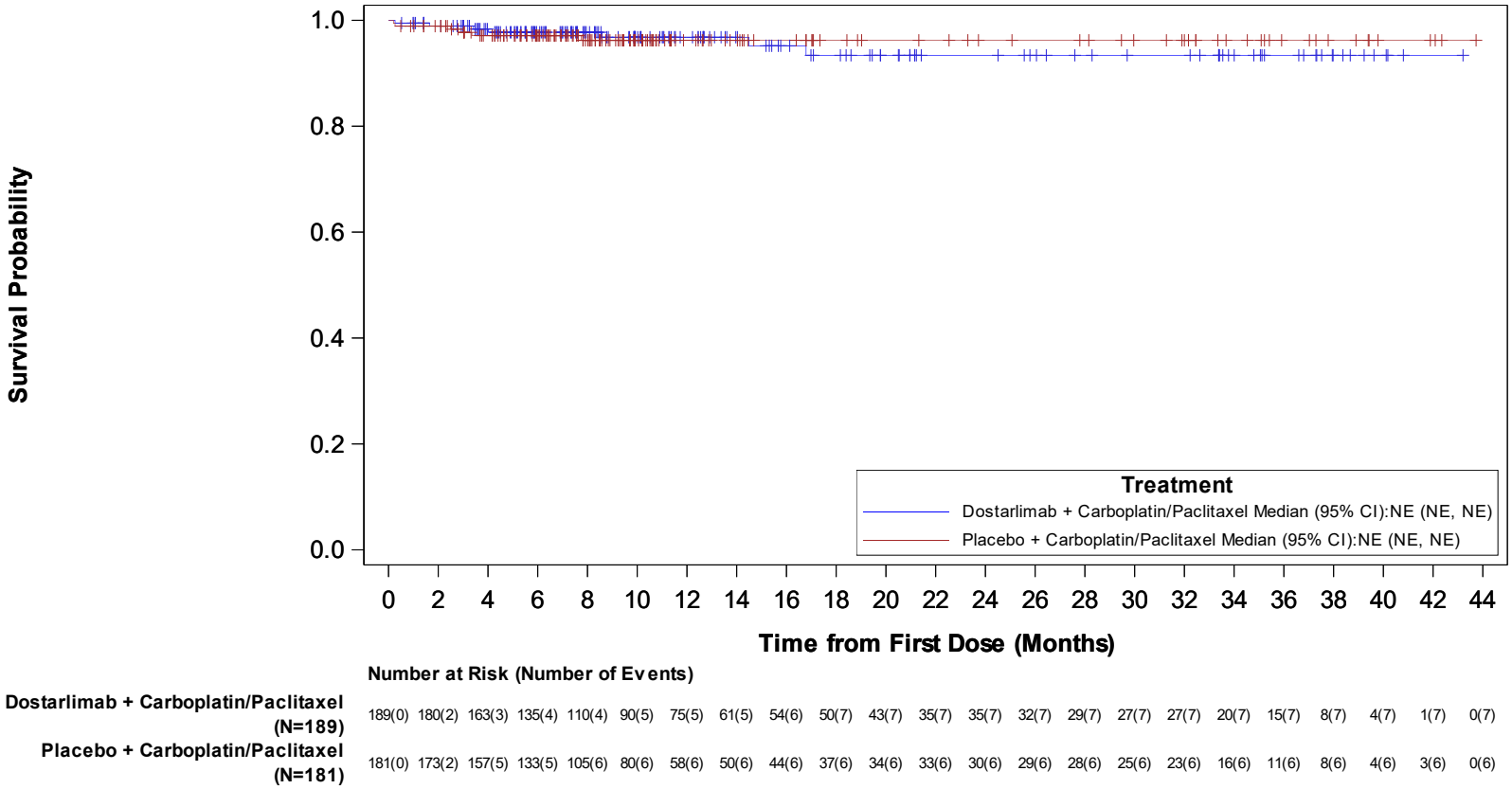
System Organ Class: Nervous system disorders



NE = Not Estimable.
Program: f_3_2102_km_ser_soc.sas, Output: f_3_2102_km_ser_soc.rtf, Generated on: 20SEP2024 08:21,
Data Cutoff Date: 22SEP2023

Figure 3.2102 Graph of Kaplan Meier Plot of Time to Treatment-Emergent Serious Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

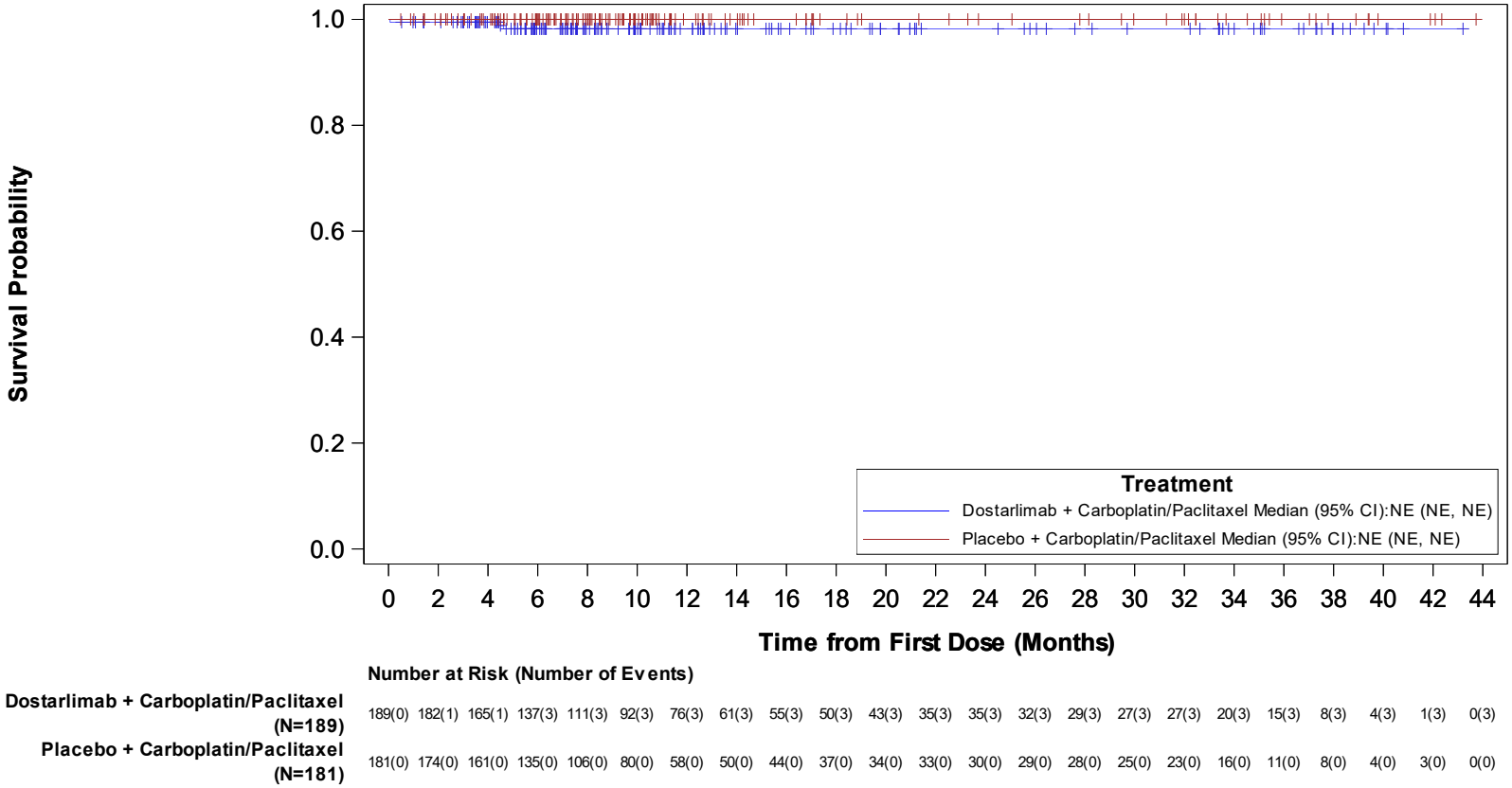
System Organ Class: Metabolism and nutrition disorders



NE = Not Estimable.

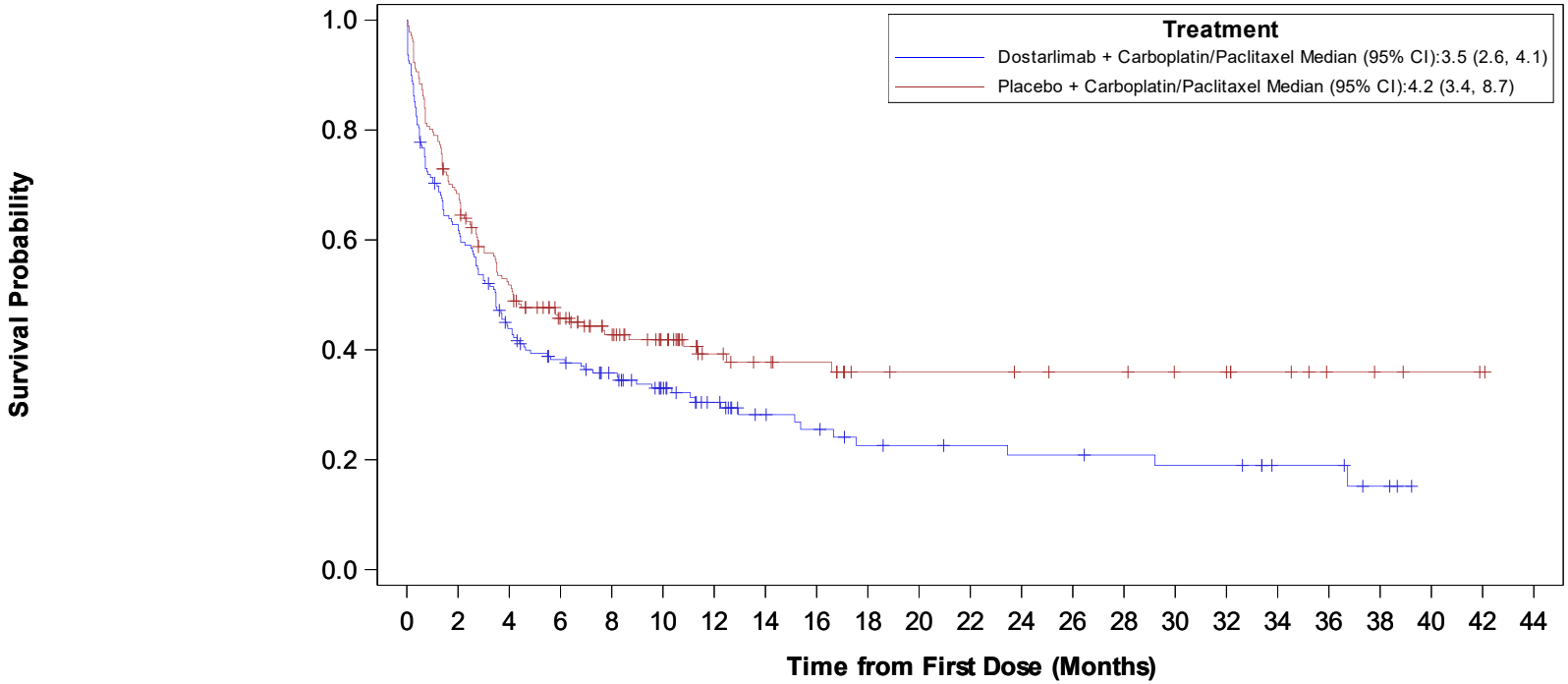
Program: f_3_2102_km_ser_soc.sas, Output: f_3_2102_km_ser_soc.rtf, Generated on: 20SEP2024 08:21,
Data Cutoff Date: 22SEP2023

Figure 3.2502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events leading to Death
(Safety Analysis Set): MMRp/MSS Subjects



NE = Not Estimable.
Program: f_3_2502_km_aedth.sas, Output: f_3_2502_km_aedth.rtf, Generated on: 20SEP2024 15:04,
Data Cutoff Date: 22SEP2023

Figure 3.2902 Graph of Kaplan Meier Curves of Time to Grade >=3 Treatment-Emergent Adverse Events
(Safety Analysis Set): MMRp/MSS Subjects



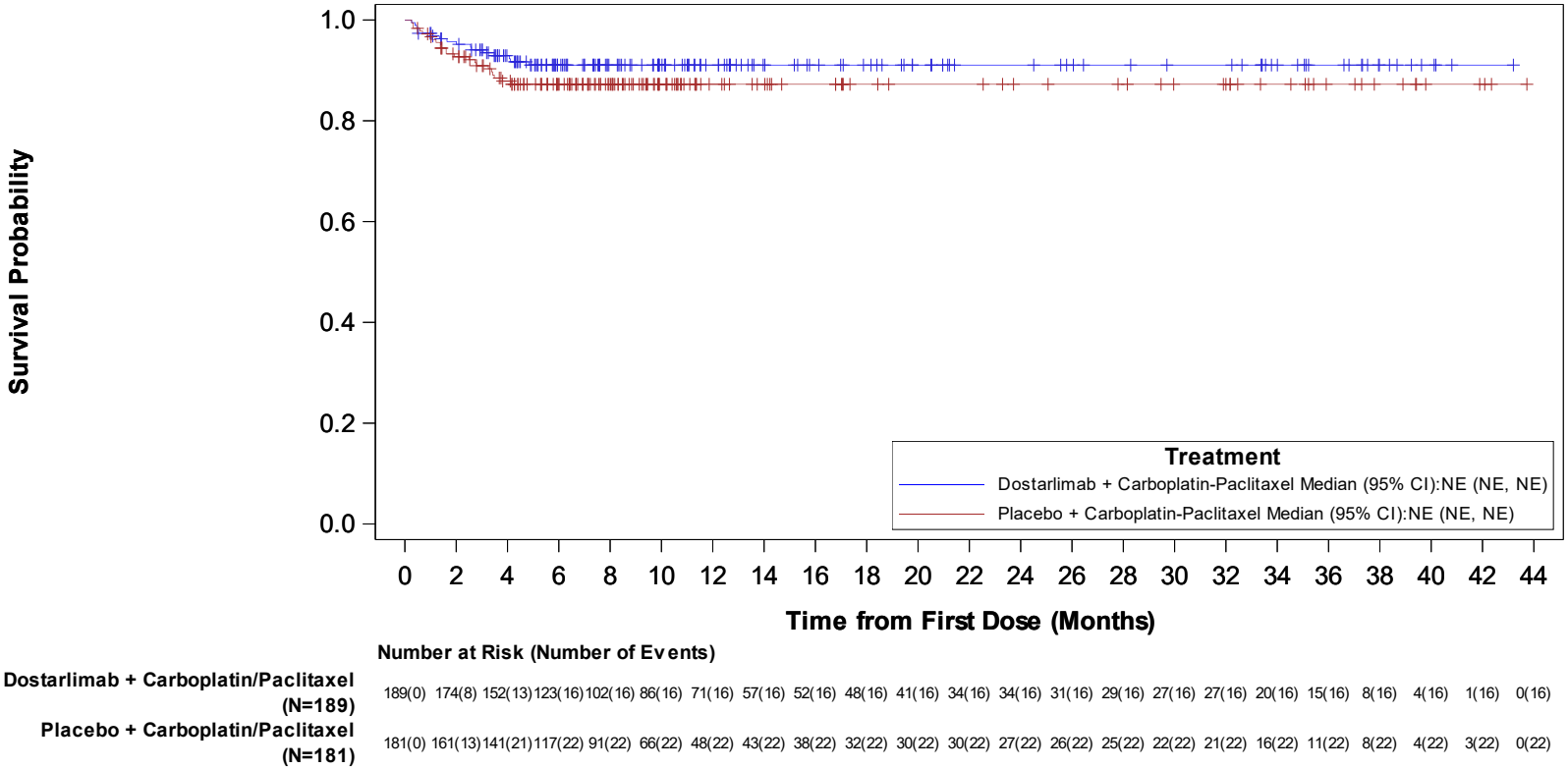
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0) 117(70) 79(105) 64(115) 54(119) 42(123) 31(126) 22(128) 19(130) 15(132) 14(132) 13(132) 12(133) 12(133) 11(133) 10(134) 10(134) 6(134) 6(134) 3(135) 0(135)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0) 122(57) 89(86) 68(96) 54(100) 42(101) 27(103) 23(104) 21(104) 15(105) 14(105) 14(105) 13(105) 12(105) 12(105) 10(105) 10(105) 7(105) 4(105) 3(105) 2(105) 1(105) 0(105)

NE = Not Estimable.
Program: f_3_2902_km_ae_ge3.sas, Output: f_3_2902_km_ae_ge3.rtf, Generated on: 20SEP2024 17:21,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

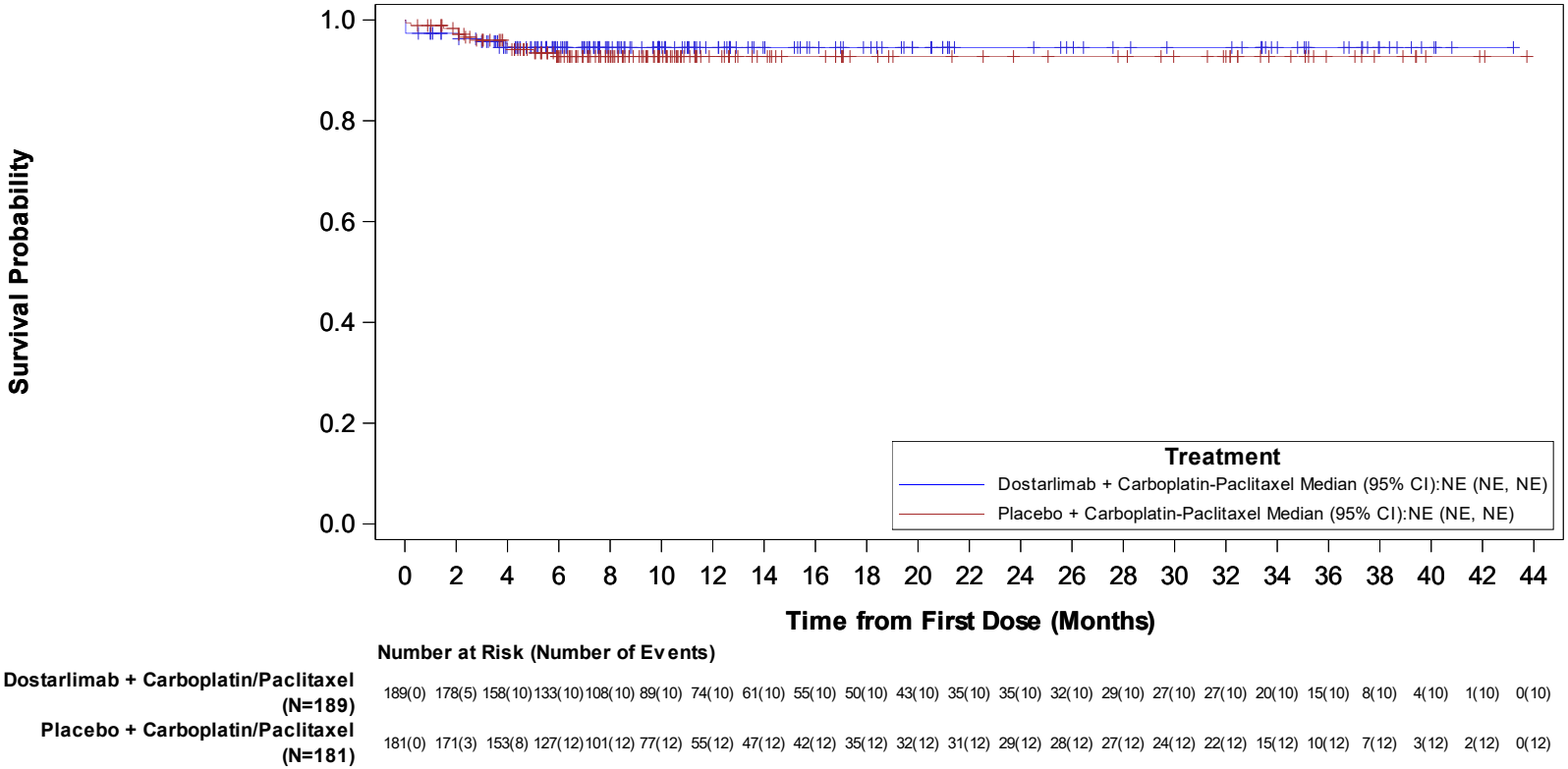
System Organ Class: Investigations
Preferred Term: Neutrophil count decreased



NE = Not Estimable.
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

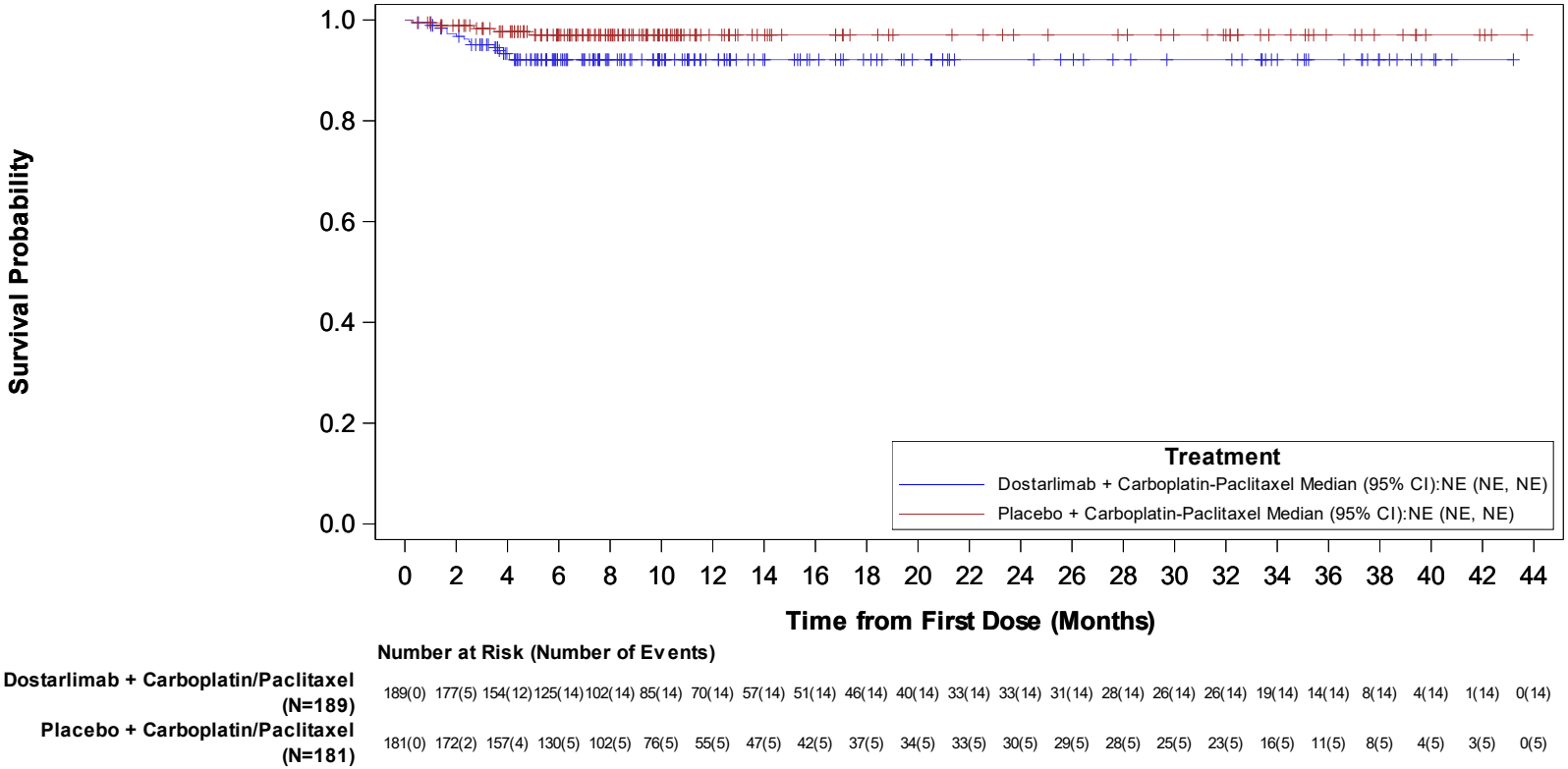
System Organ Class: Investigations
Preferred Term: Lymphocyte count decreased



NE = Not Estimable.
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

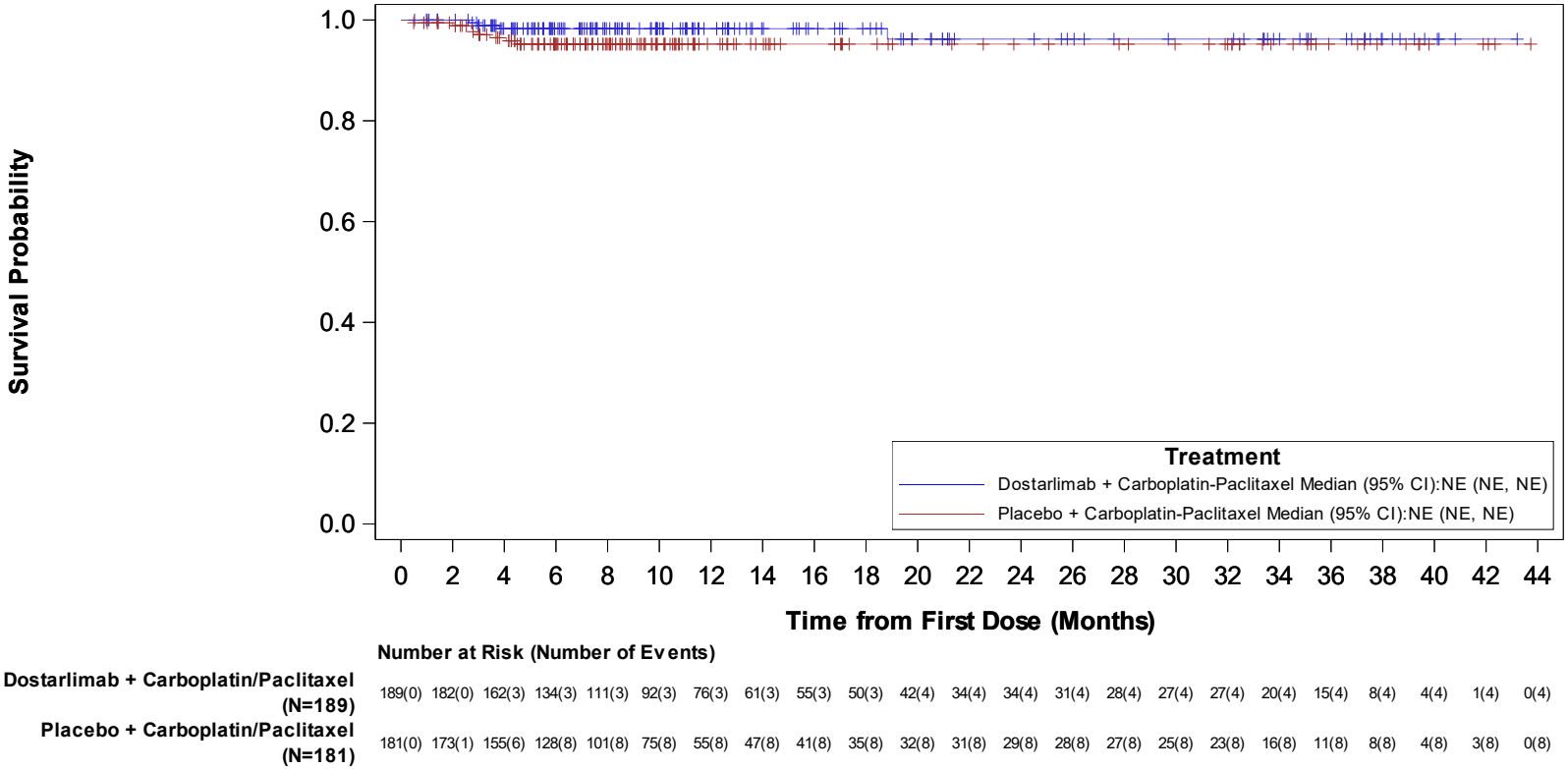
System Organ Class: Investigations
Preferred Term: White blood cell count decreased



NE = Not Estimable.
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

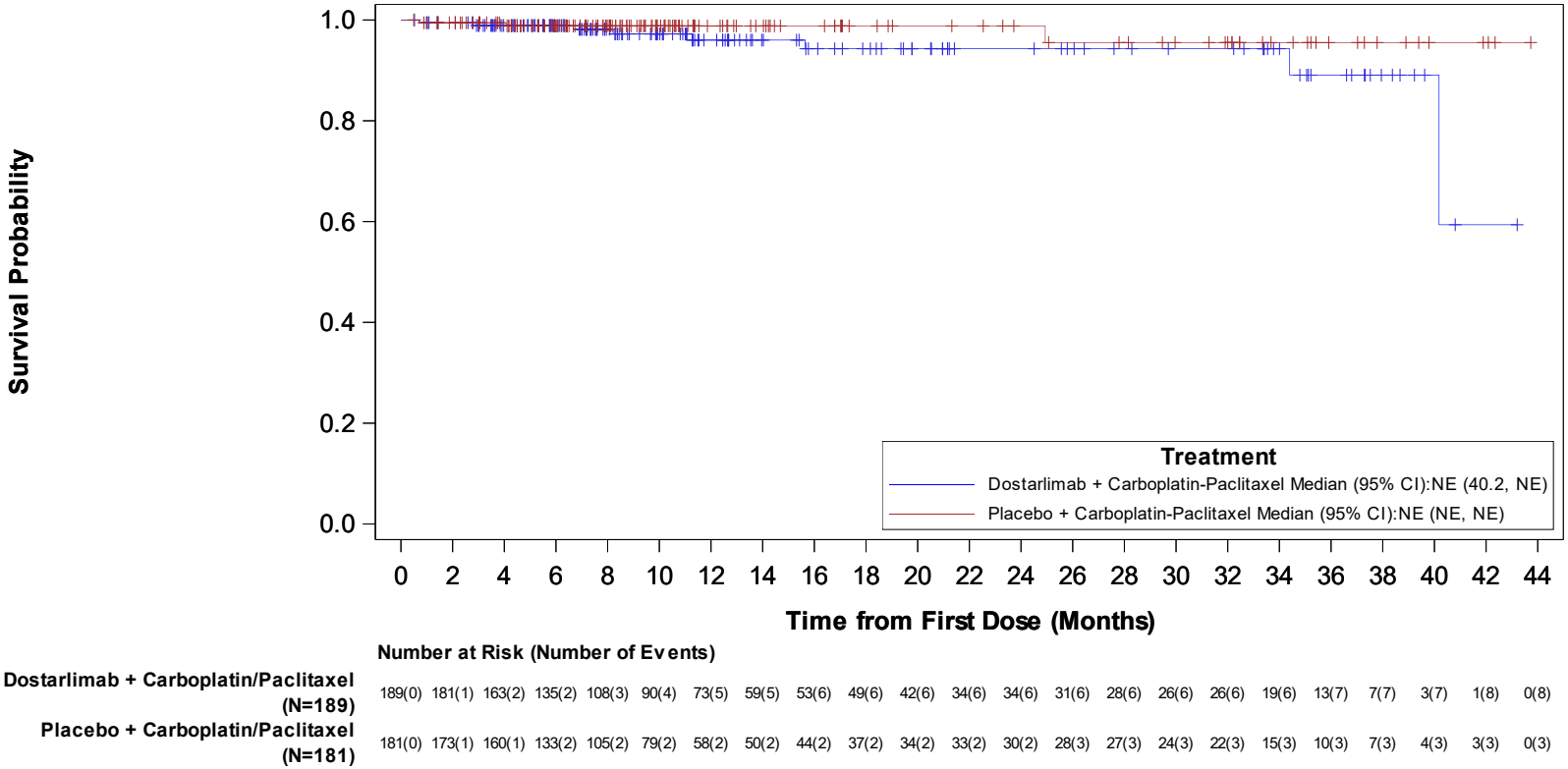
System Organ Class: Investigations
Preferred Term: Platelet count decreased



NE = Not Estimable.
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

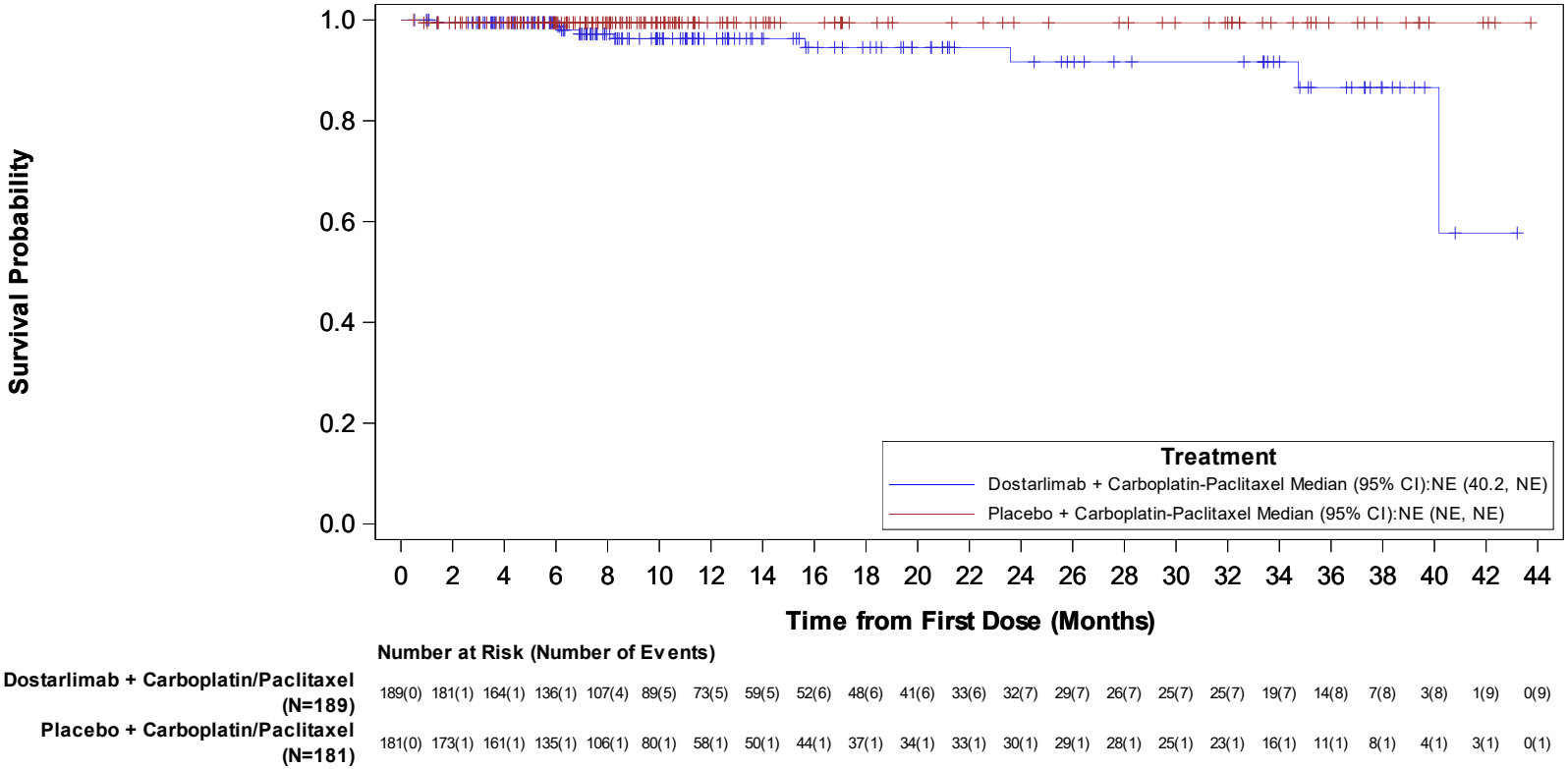
System Organ Class: Investigations
Preferred Term: Lipase increased



NE = Not Estimable.
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Amylase increased



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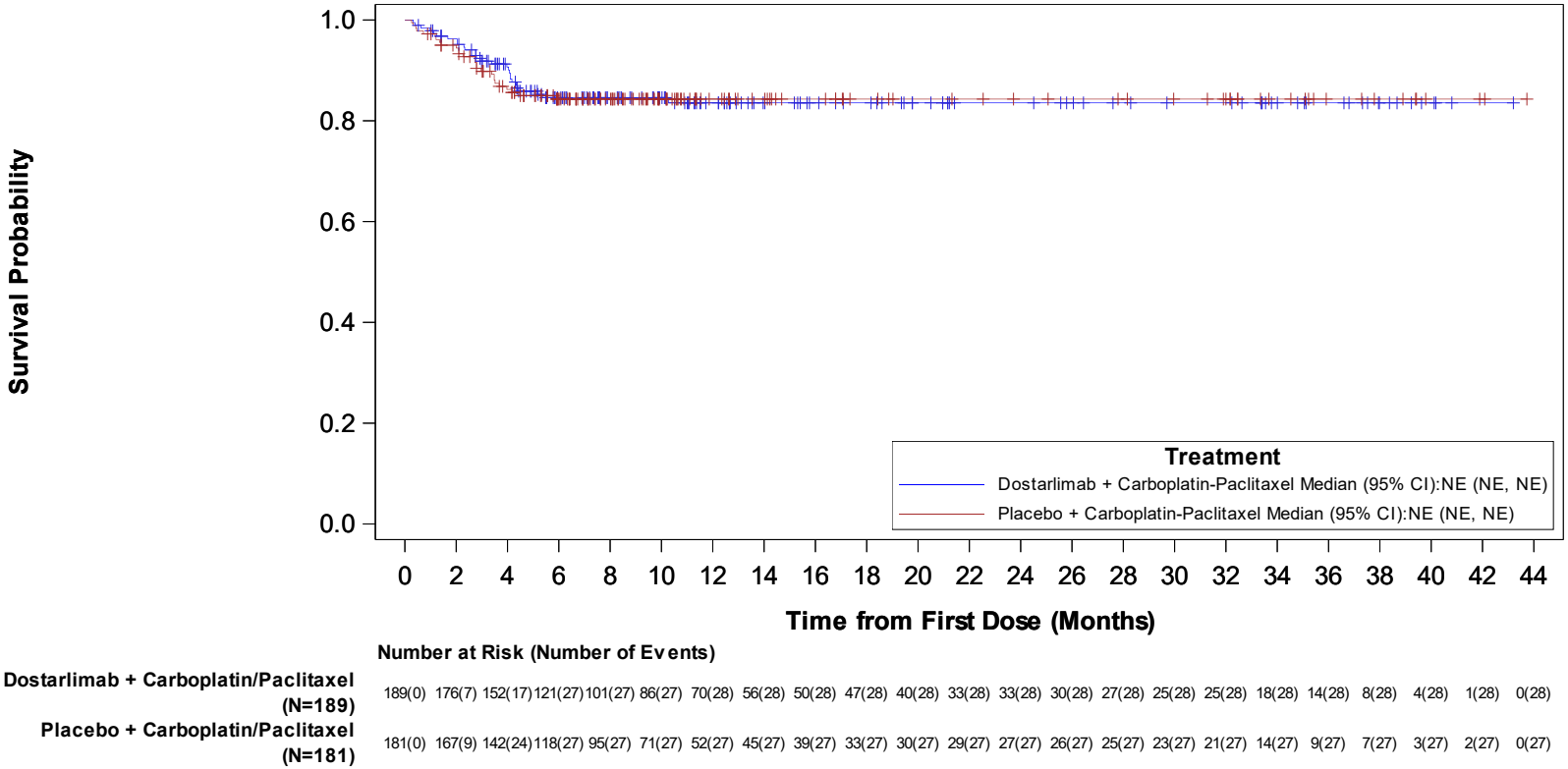
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

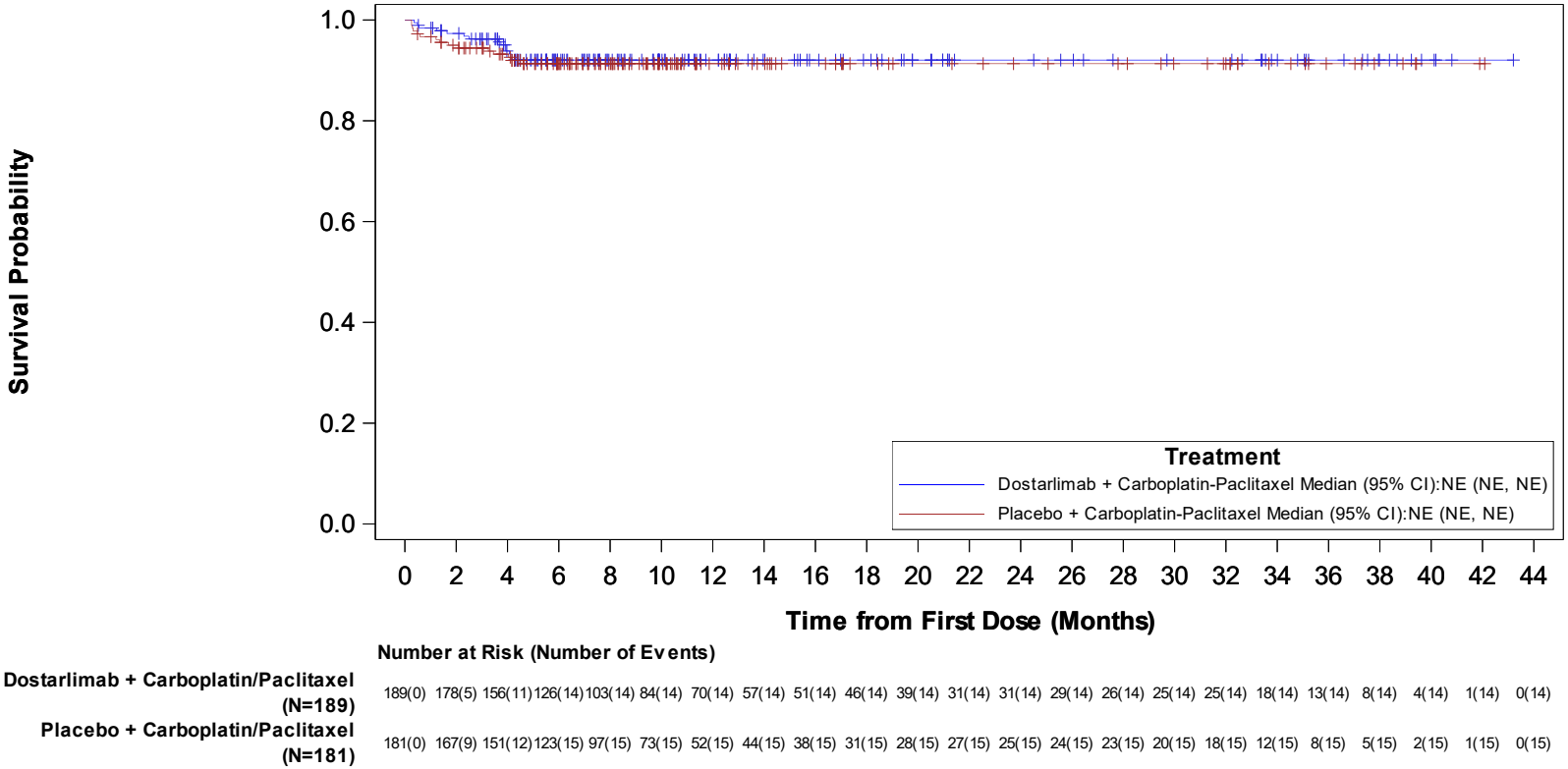
System Organ Class: Blood and lymphatic system disorders
Preferred Term: Anaemia



NE = Not Estimable.
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Blood and lymphatic system disorders
Preferred Term: Neutropenia



NE = Not Estimable.
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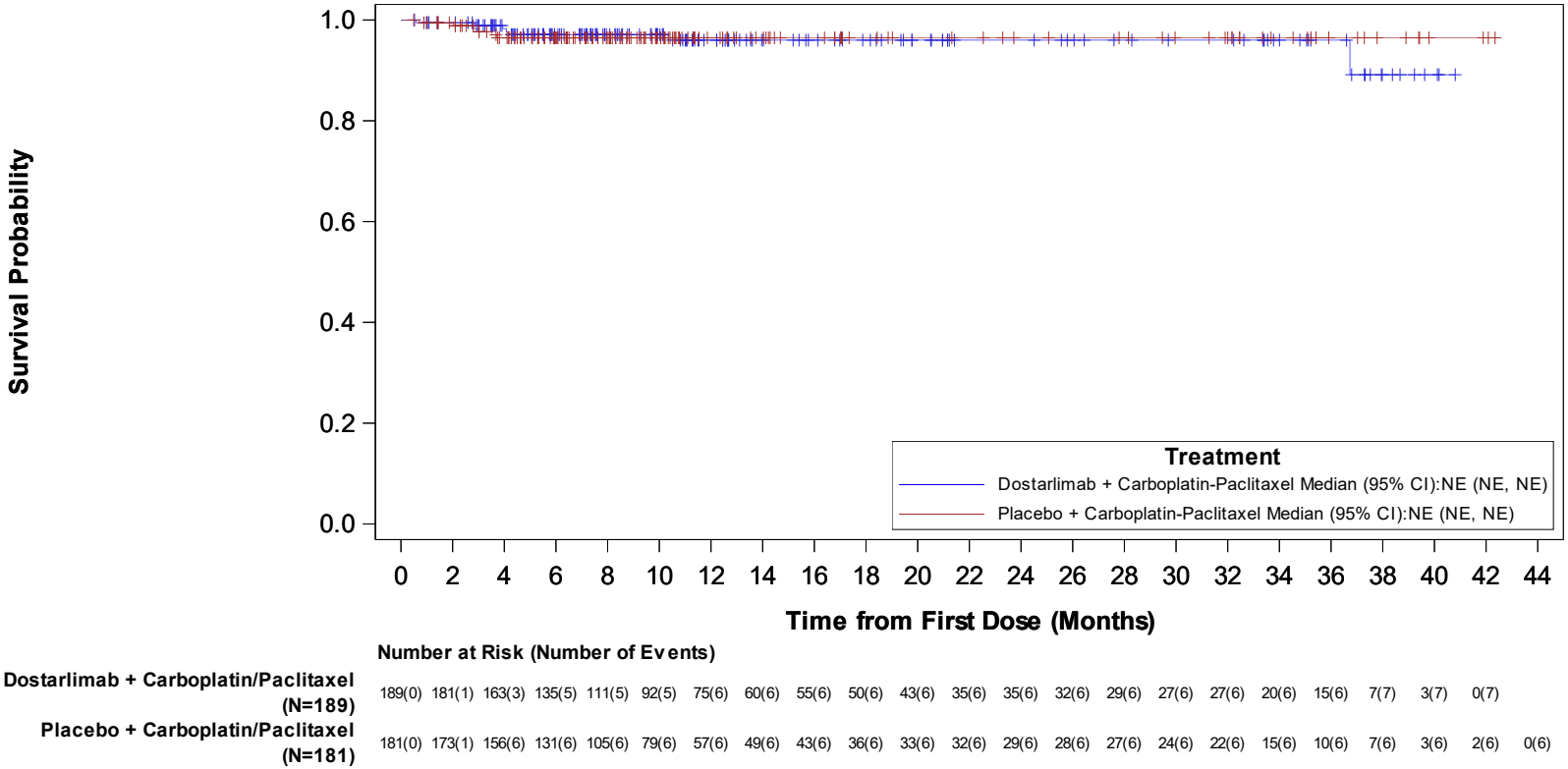
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

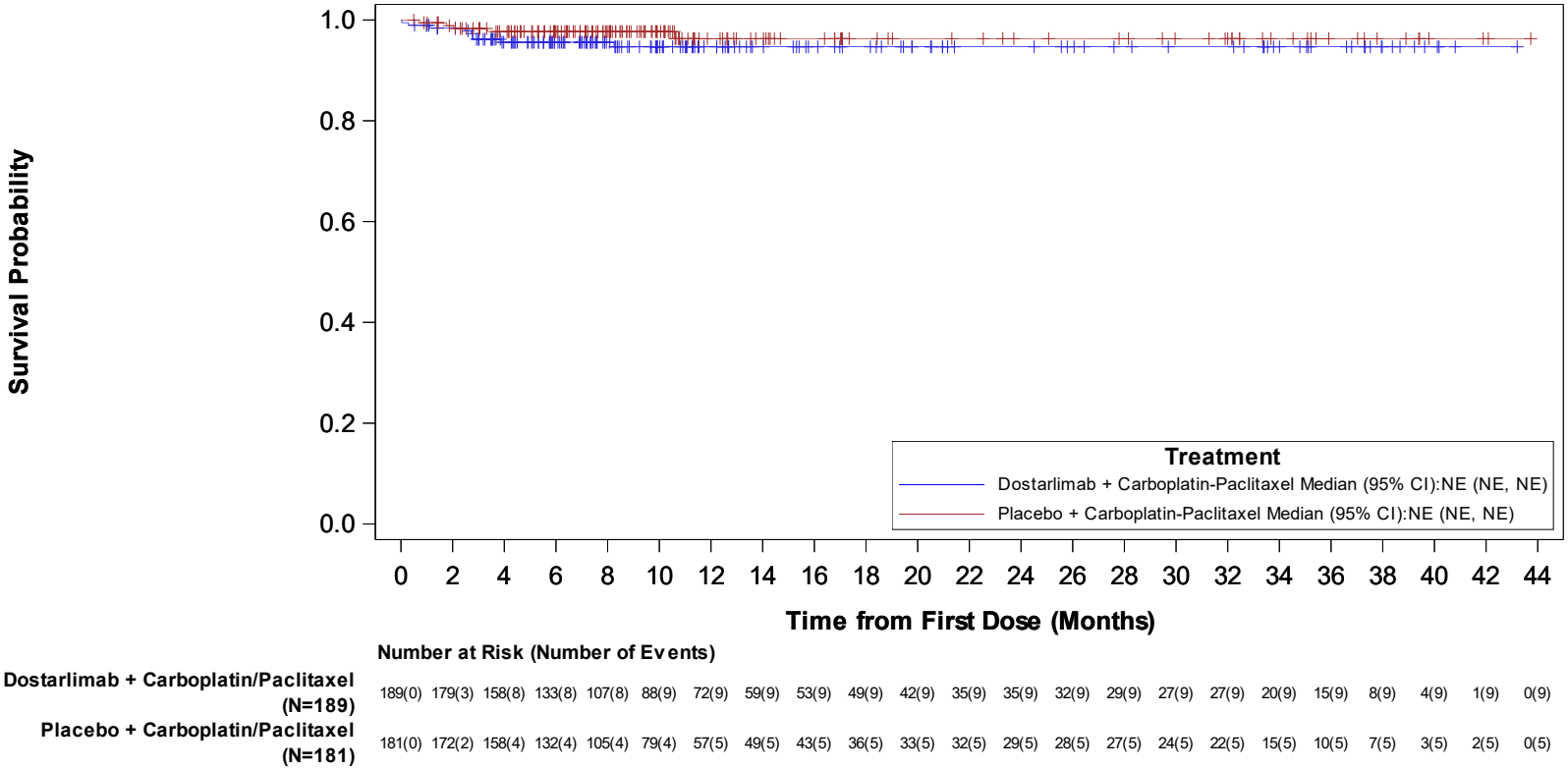
System Organ Class: Blood and lymphatic system disorders
Preferred Term: Thrombocytopenia



NE = Not Estimable.
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

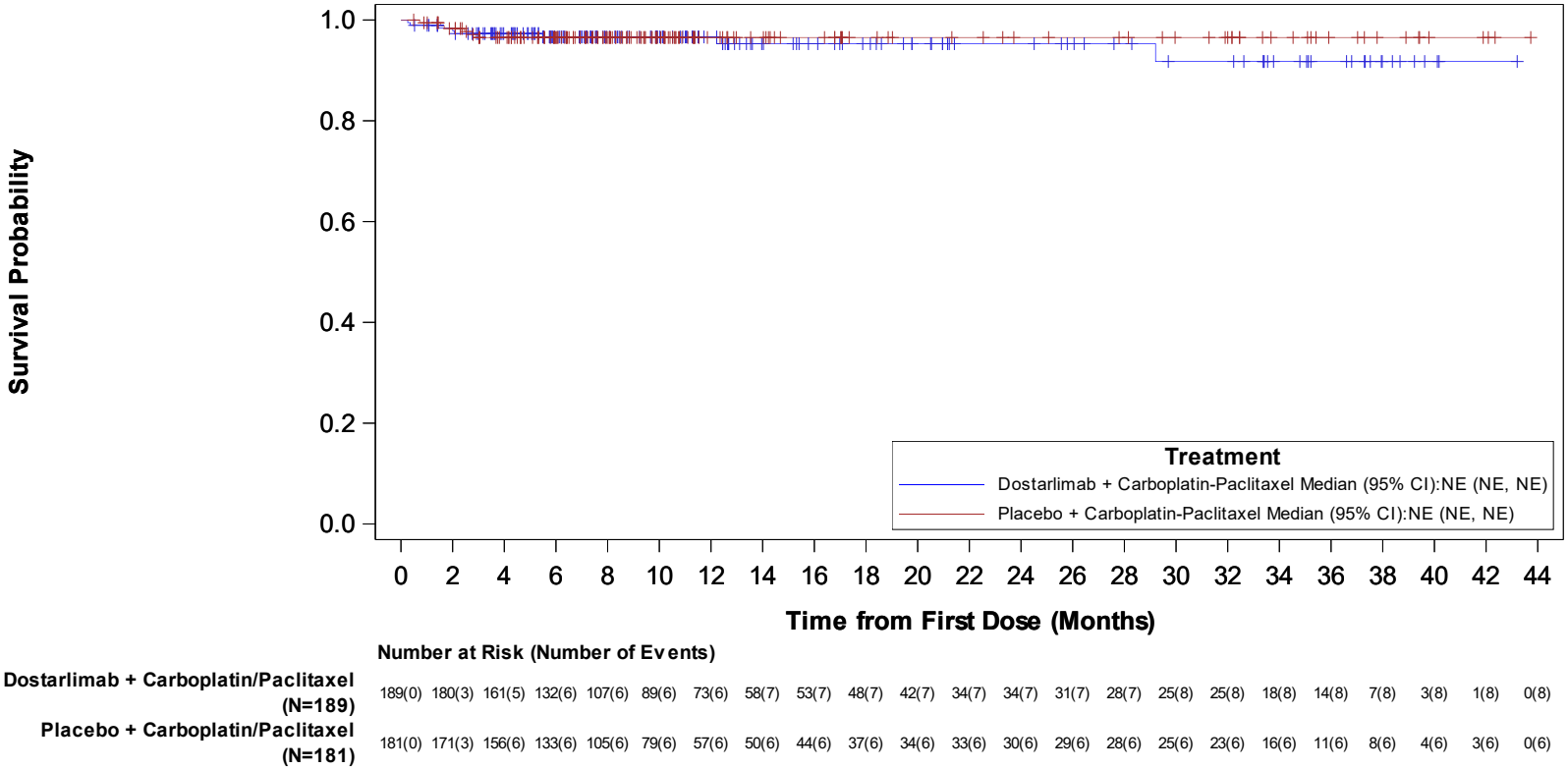
System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypokalaemia



NE = Not Estimable.
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

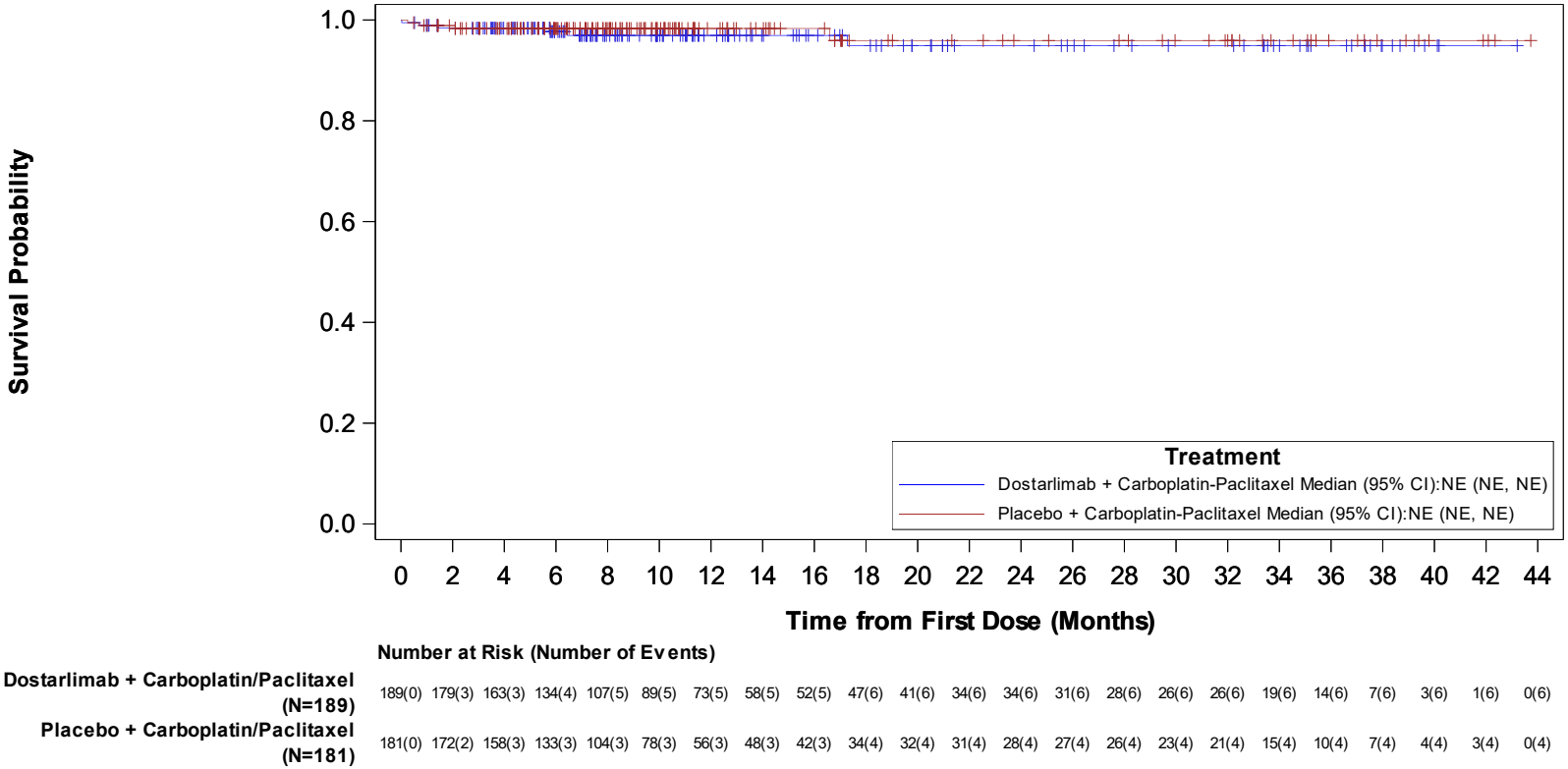
System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hyponatraemia



NE = Not Estimable.
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

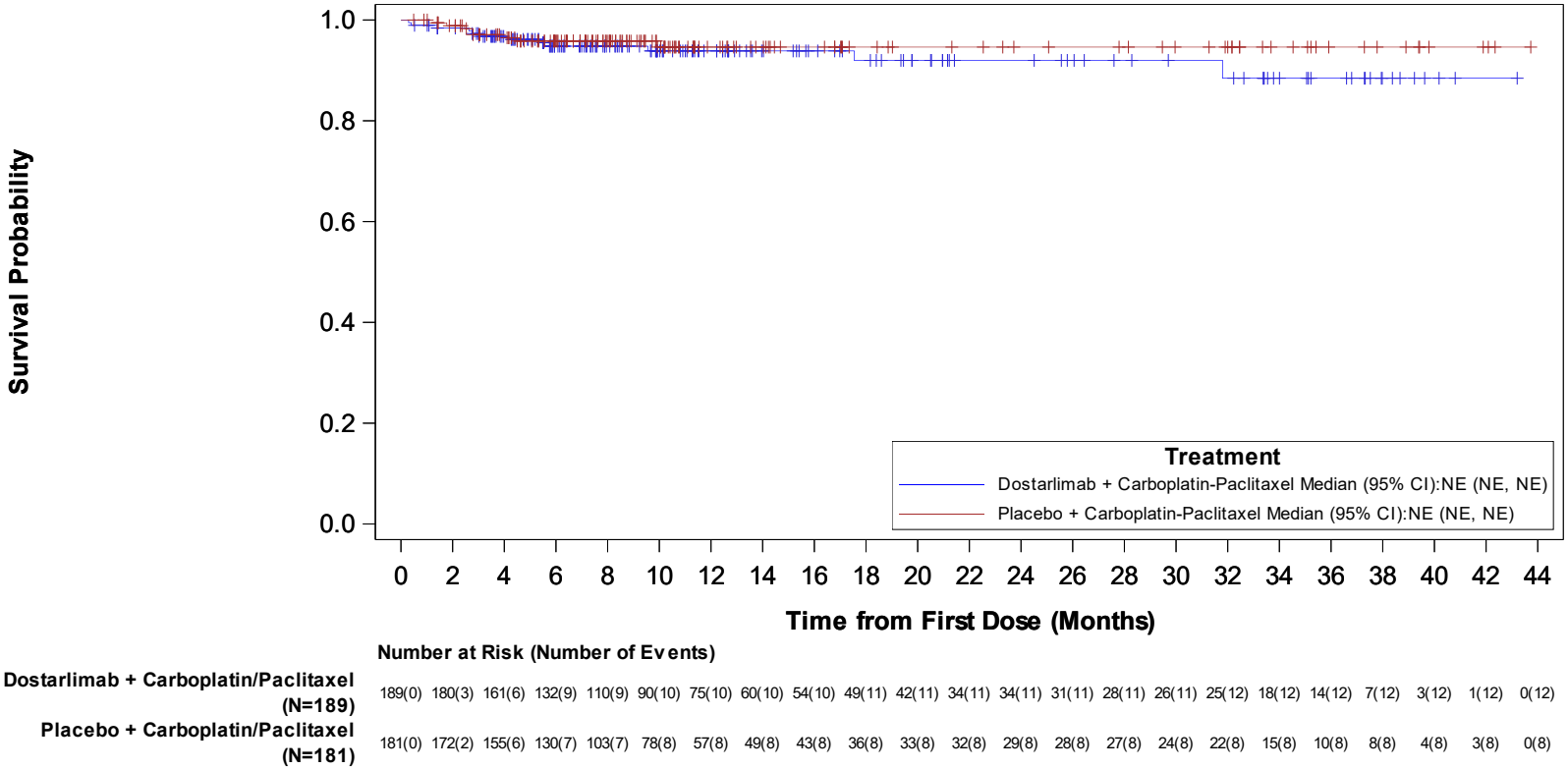
System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hyperglycaemia



NE = Not Estimable.
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

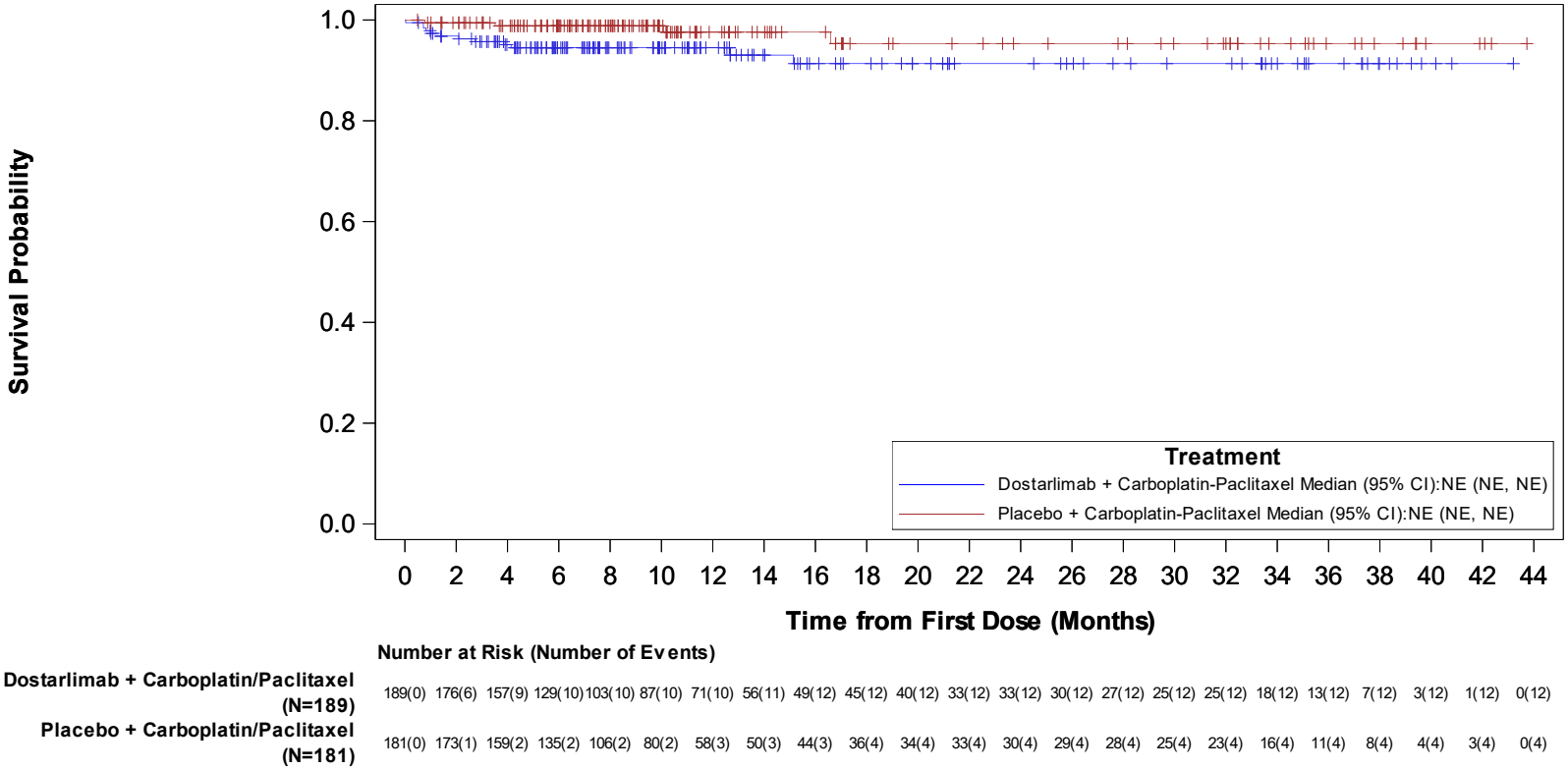
System Organ Class: Respiratory, thoracic and mediastinal disorders
Preferred Term: Pulmonary embolism



NE = Not Estimable.
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

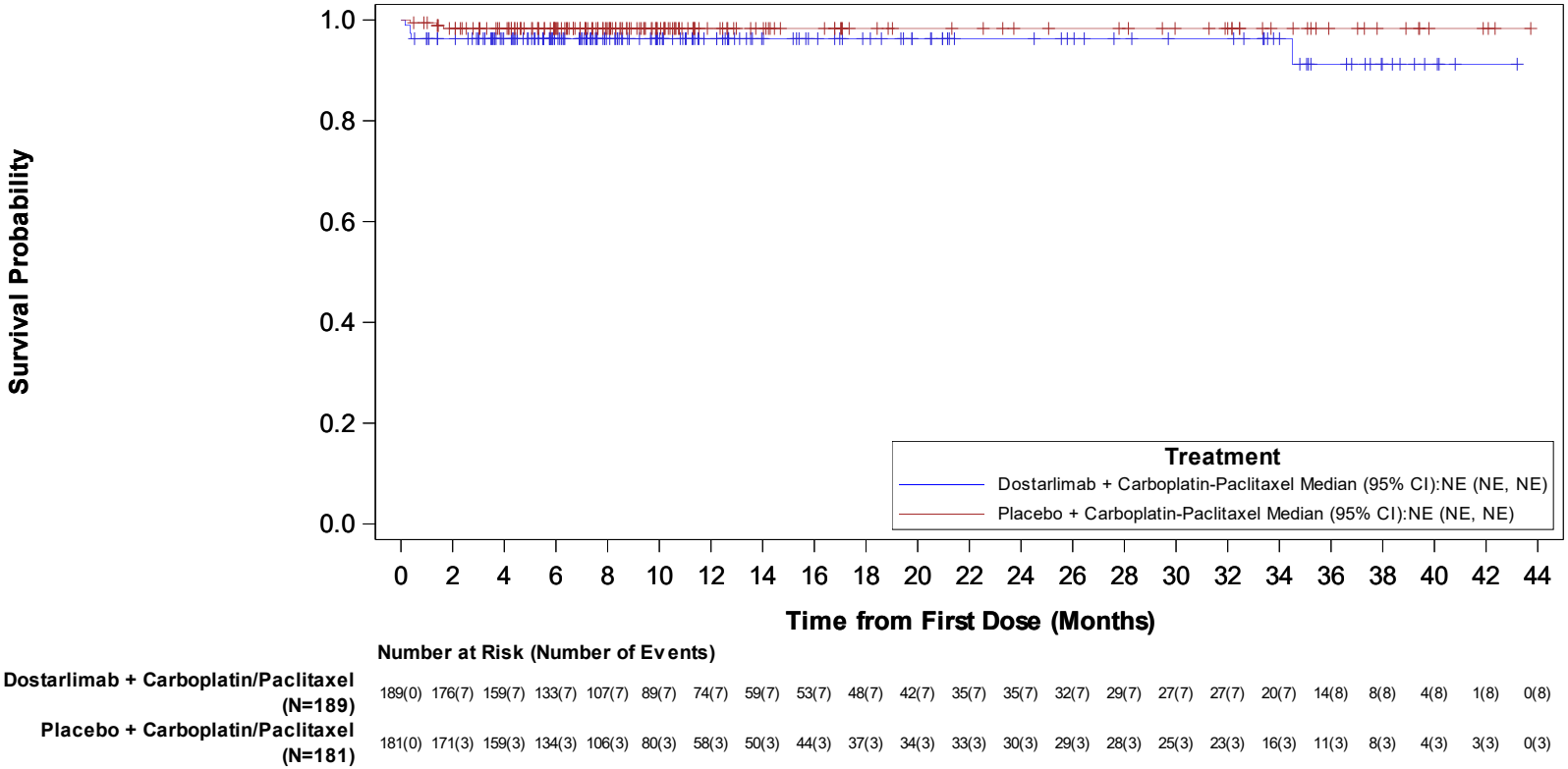
System Organ Class: Vascular disorders
Preferred Term: Hypertension



NE = Not Estimable.
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3302 Kaplan Meier Plot of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Analysis Set): MMRp/MSS Subjects

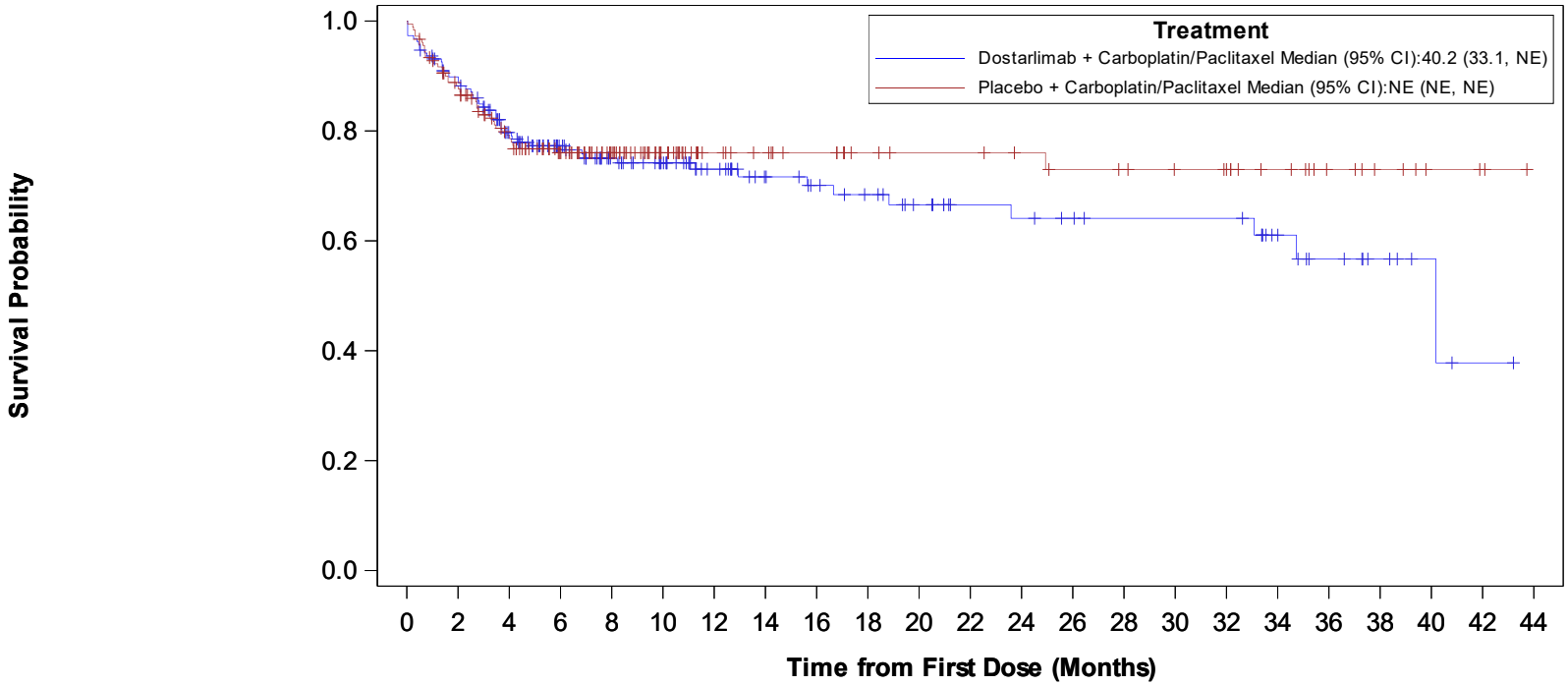
System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash



NE = Not Estimable.
Program: f_3_3302_km_ttae3_socpt.sas, Output: f_3_3302_km_ttae3_socpt.rtf, Generated on: 20SEP2024 08:20,
Data Cutoff Date: 22SEP2023

Figure 3.3702 Graph of Kaplan Meier Curves of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations



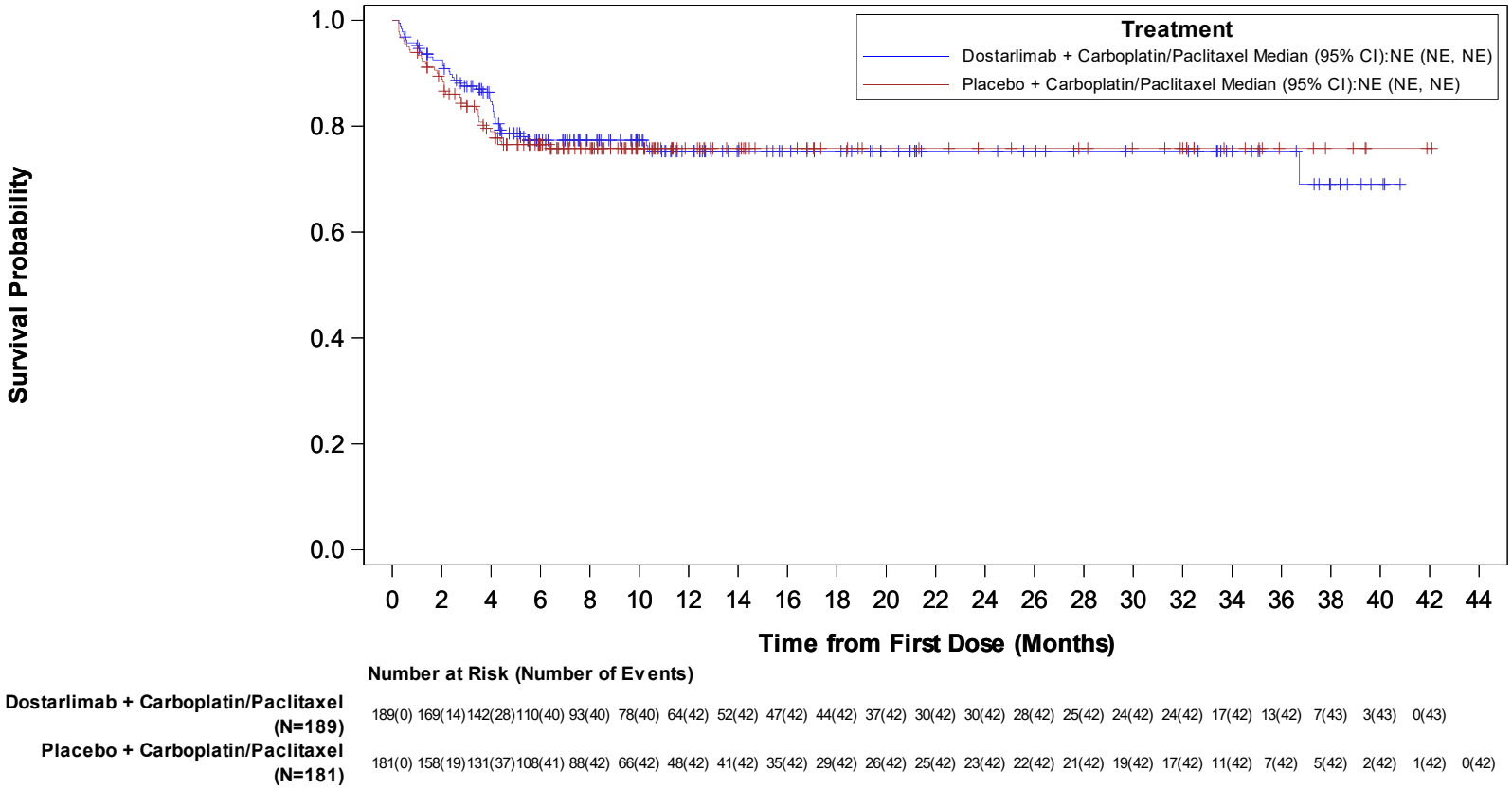
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	164(19)	133(37)	107(41)	87(44)	75(45)	60(46)	48(47)	43(48)	39(49)	33(50)	27(50)	26(51)	24(51)	22(51)	22(51)	22(51)	15(52)	10(53)	6(53)	3(53)	1(54)	0(54)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	153(21)	127(36)	103(41)	81(41)	58(41)	42(41)	38(41)	34(41)	29(41)	27(41)	27(41)	25(41)	23(42)	22(42)	20(42)	19(42)	14(42)	9(42)	6(42)	3(42)	2(42)	0(42)

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_3702_km_ae_ge3_soc.sas, Output: f_3_3702_km_ae_ge3_soc.rtf, Generated on: 20SEP2024 12:02,
Data Cutoff Date: 22SEP2023

Figure 3.3702 Graph of Kaplan Meier Curves of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

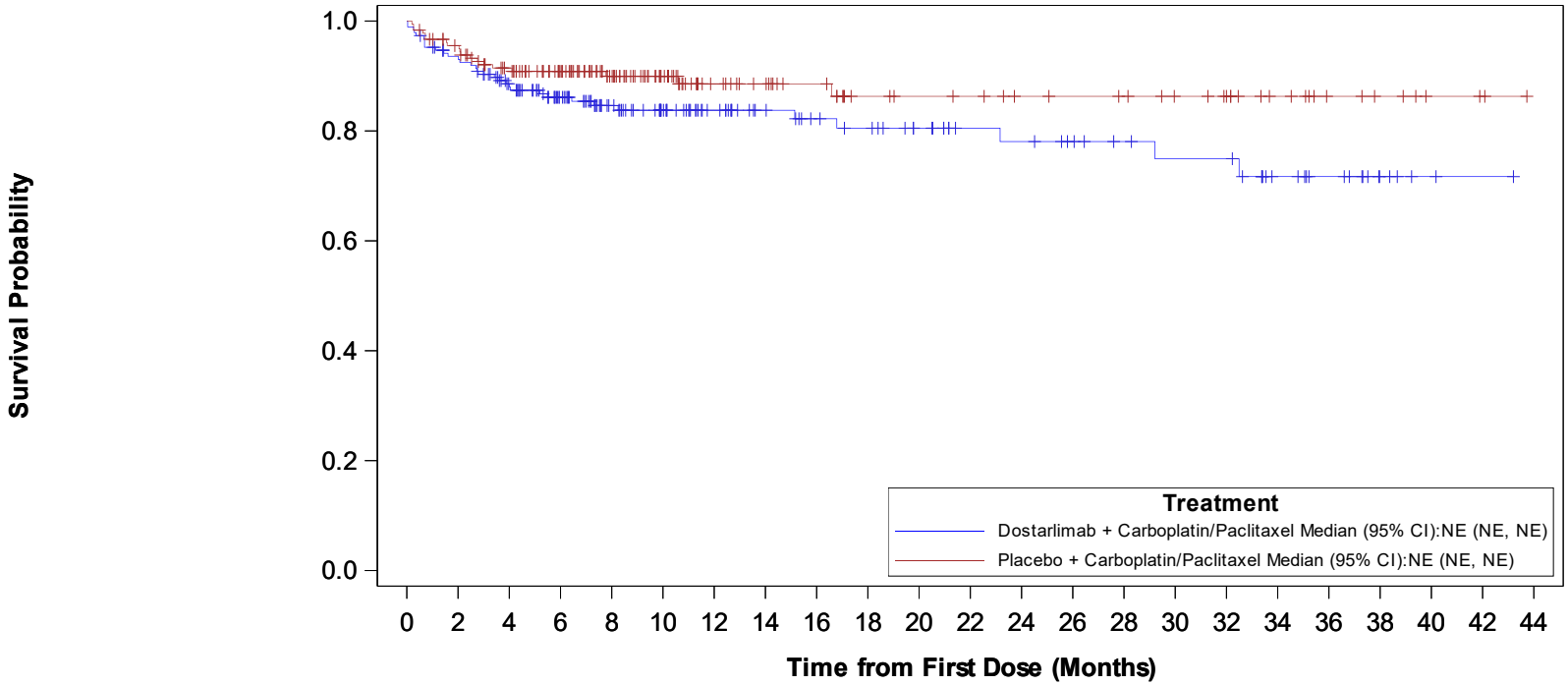
System Organ Class: Blood and lymphatic system disorders



Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_3702_km_ae_ge3_soc.sas, Output: f_3_3702_km_ae_ge3_soc.rtf, Generated on: 20SEP2024 12:02,
Data Cutoff Date: 22SEP2023

Figure 3.3702 Graph of Kaplan Meier Curves of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

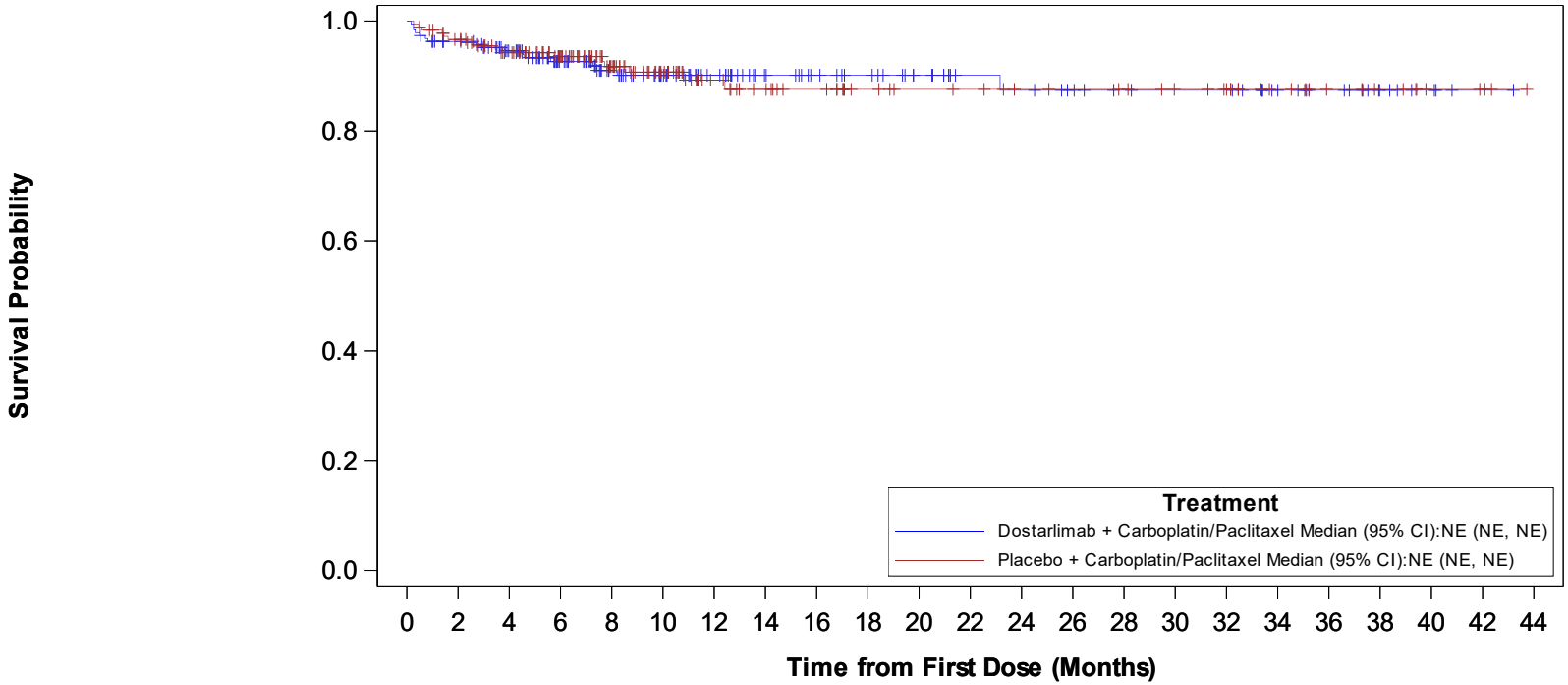
System Organ Class: Metabolism and nutrition disorders



Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_3702_km_ae_ge3_soc.sas, Output: f_3_3702_km_ae_ge3_soc.rtf, Generated on: 20SEP2024 12:02,
Data Cutoff Date: 22SEP2023

Figure 3.3702 Graph of Kaplan Meier Curves of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

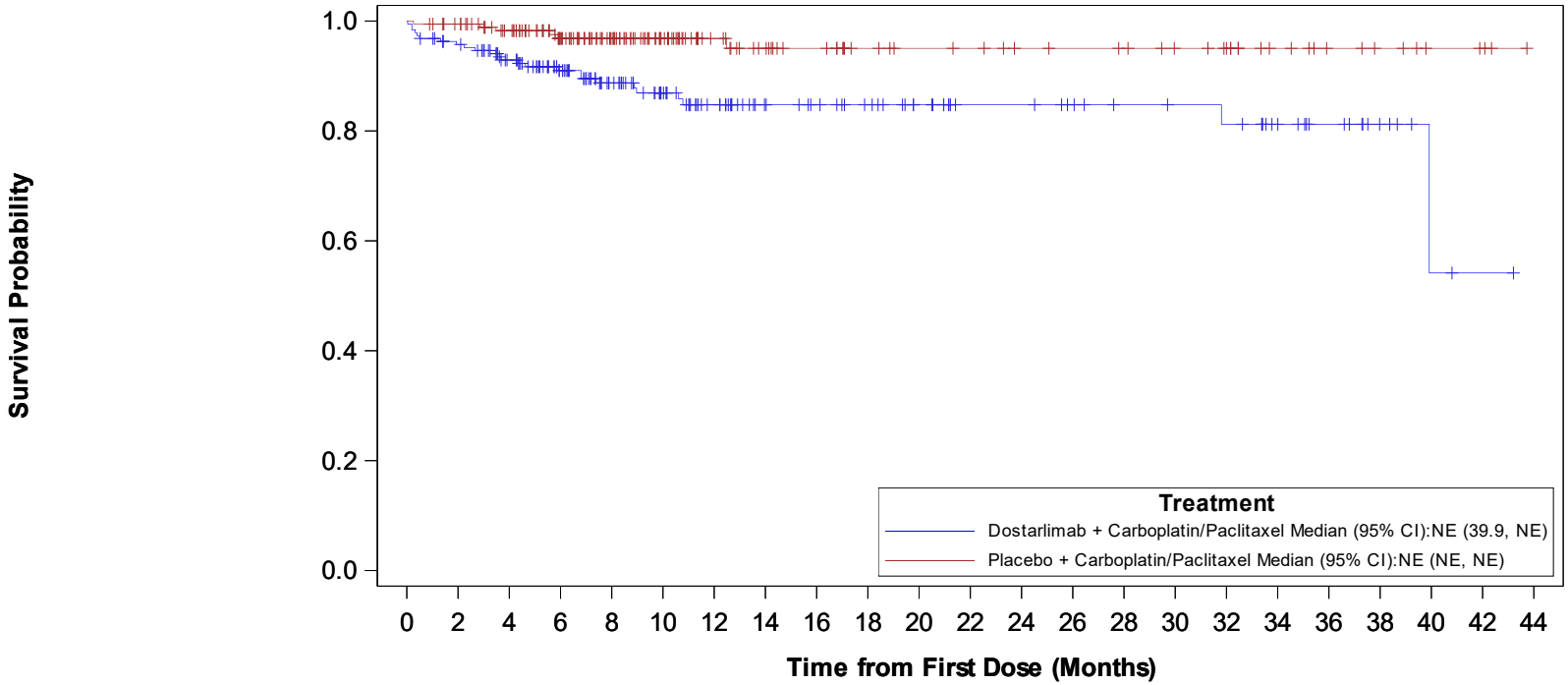
System Organ Class: Gastrointestinal disorders



Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_3702_km_ae_ge3_soc.sas, Output: f_3_3702_km_ae_ge3_soc.rtf, Generated on: 20SEP2024 12:02,
Data Cutoff Date: 22SEP2023

Figure 3.3702 Graph of Kaplan Meier Curves of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations



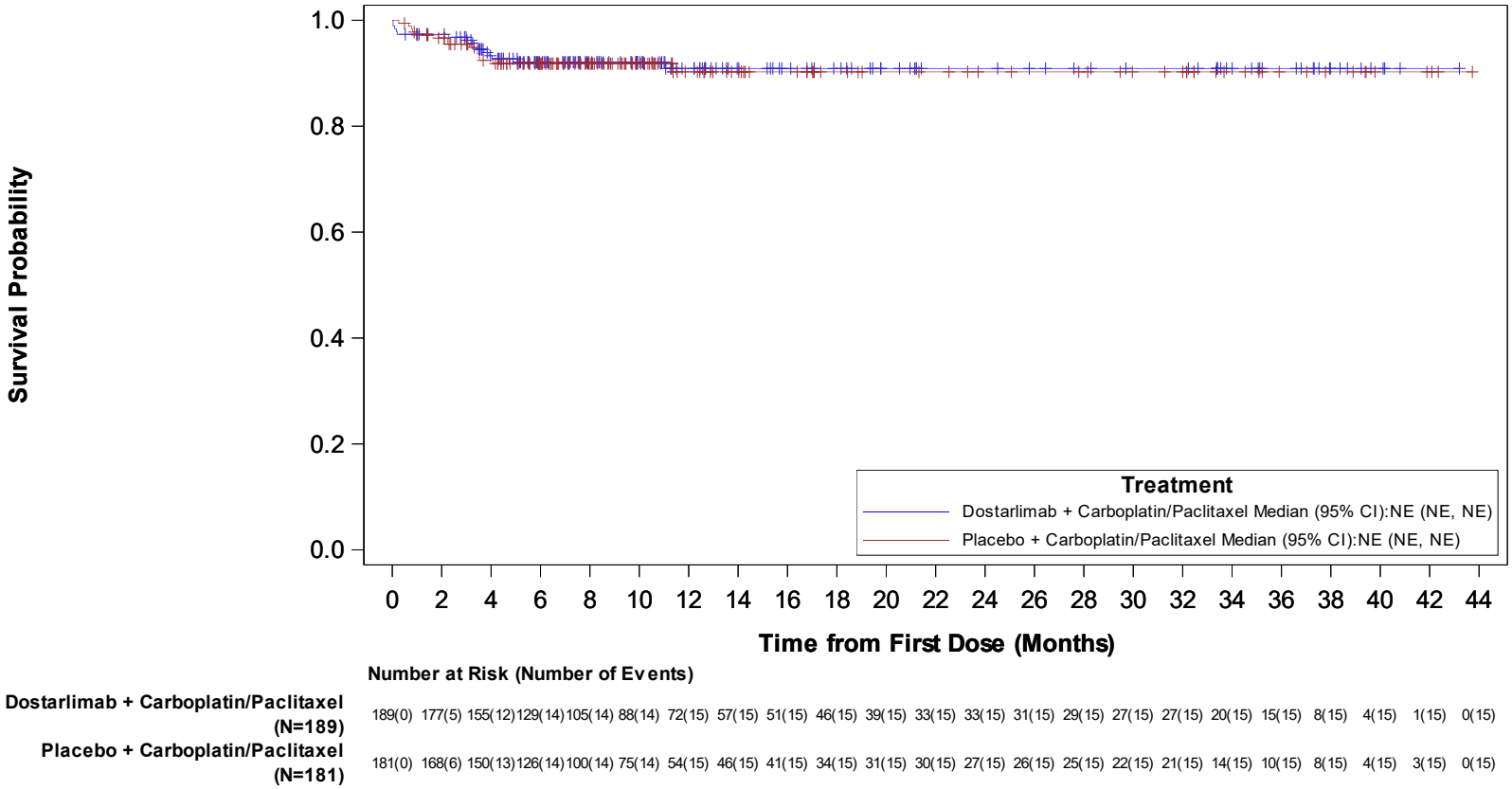
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	175(8)	156(13)	130(16)	105(19)	86(21)	70(23)	55(23)	51(23)	46(23)	39(23)	31(23)	31(23)	28(23)	25(23)	24(23)	23(24)	17(24)	12(24)	6(24)	2(25)	1(25)	0(25)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	174(1)	159(3)	131(5)	104(5)	78(5)	56(5)	47(6)	41(6)	34(6)	31(6)	30(6)	27(6)	26(6)	25(6)	22(6)	20(6)	13(6)	9(6)	7(6)	4(6)	3(6)	0(6)

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_3702_km_ae_ge3_soc.sas, Output: f_3_3702_km_ae_ge3_soc.rtf, Generated on: 20SEP2024 12:02,
Data Cutoff Date: 22SEP2023

Figure 3.3702 Graph of Kaplan Meier Curves of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

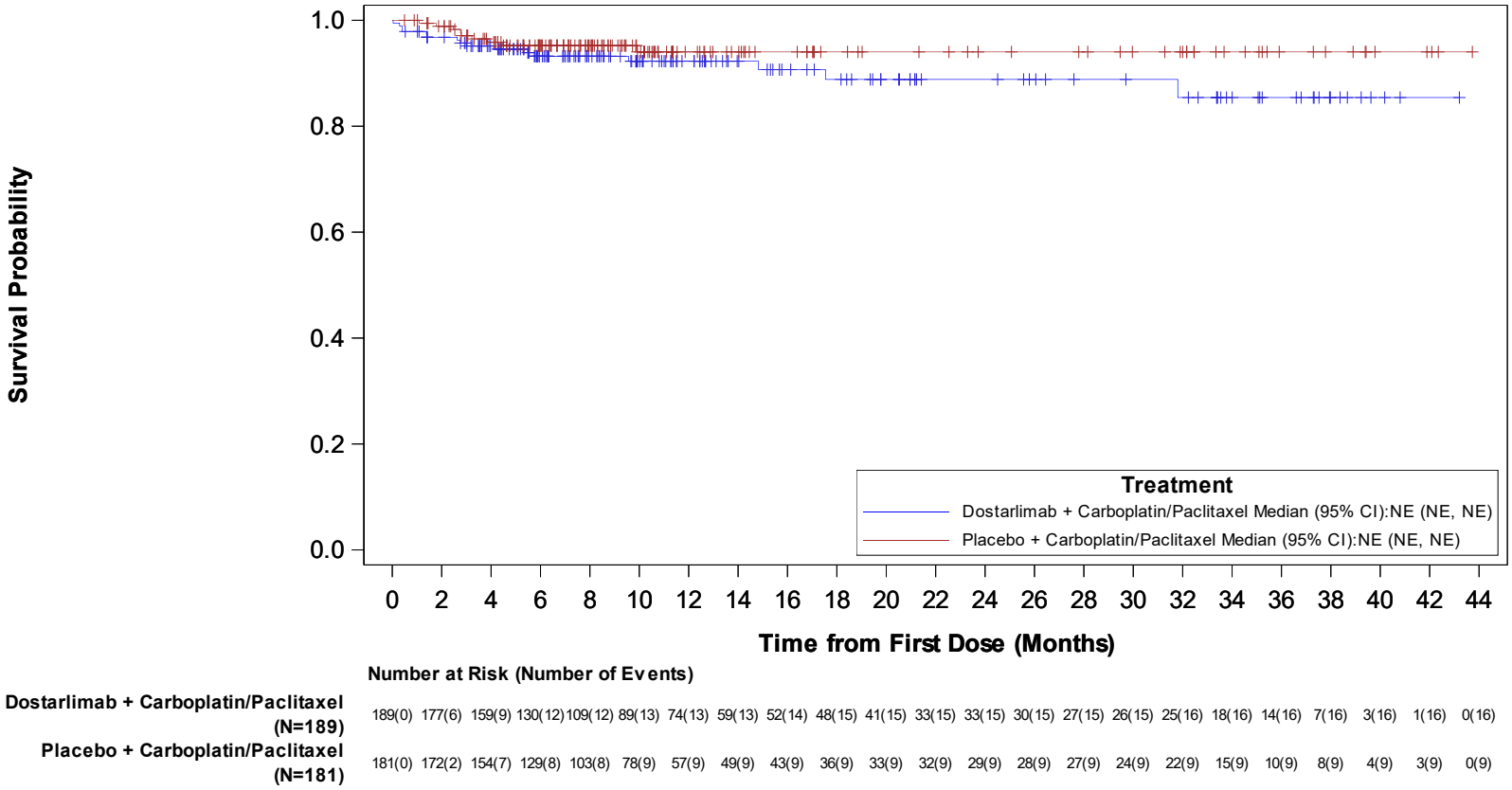
System Organ Class: Nervous system disorders



Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_3702_km_ae_ge3_soc.sas, Output: f_3_3702_km_ae_ge3_soc.rtf, Generated on: 20SEP2024 12:02,
Data Cutoff Date: 22SEP2023

Figure 3.3702 Graph of Kaplan Meier Curves of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

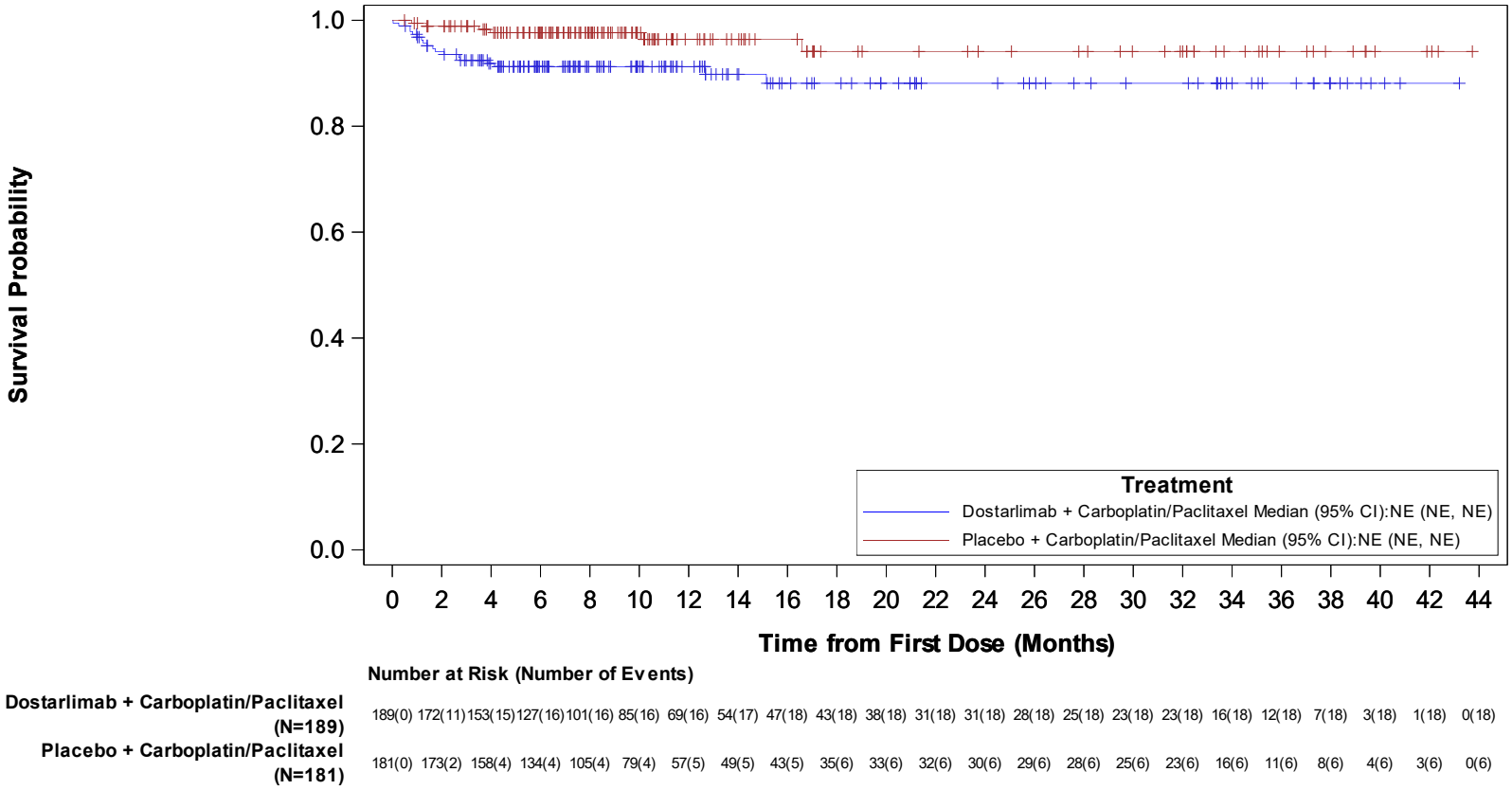
System Organ Class: Respiratory, thoracic and mediastinal disorders



Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_3702_km_ae_ge3_soc.sas, Output: f_3_3702_km_ae_ge3_soc.rtf, Generated on: 20SEP2024 12:02,
Data Cutoff Date: 22SEP2023

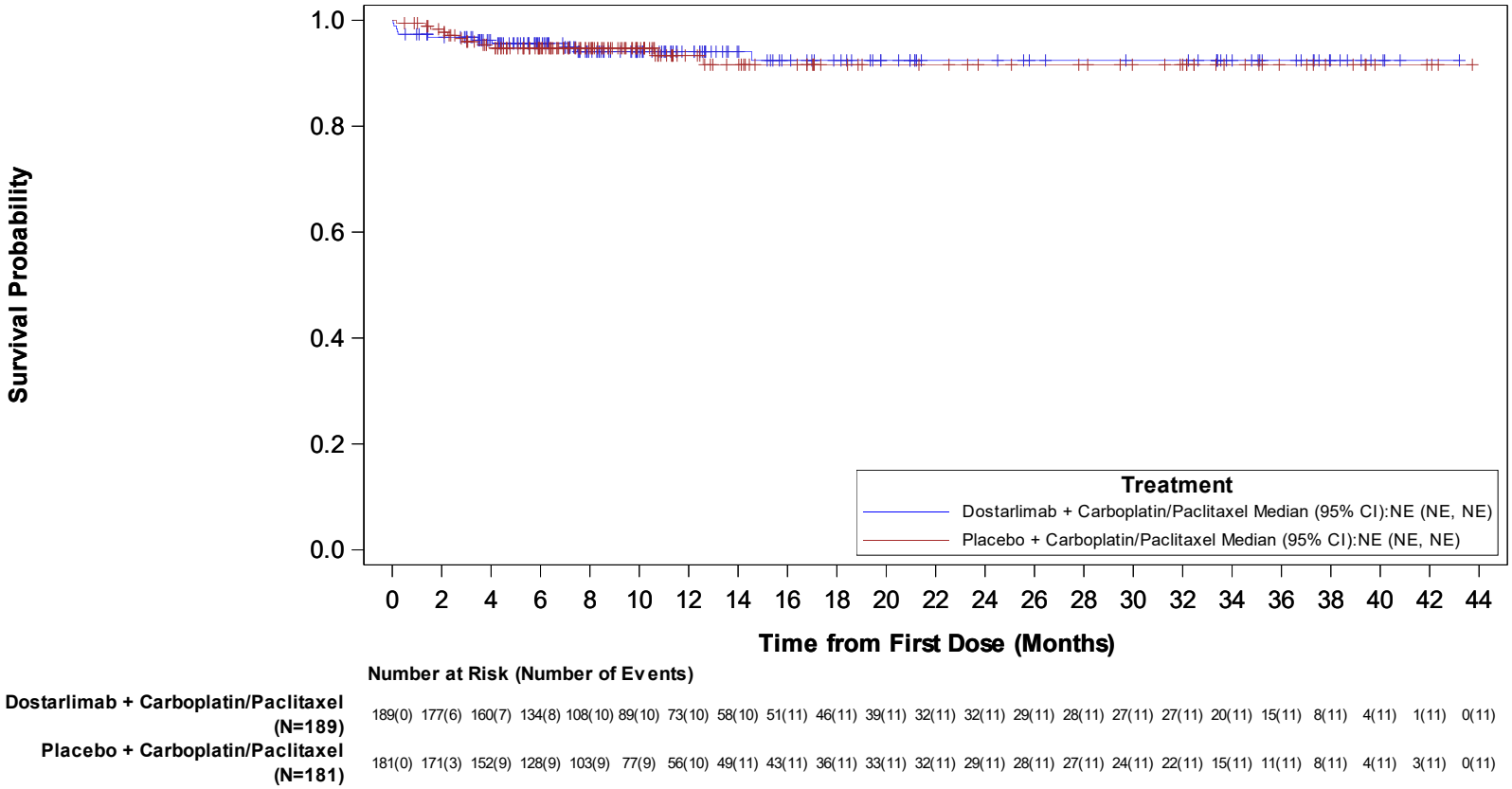
Figure 3.3702 Graph of Kaplan Meier Curves of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders



Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_3702_km_ae_ge3_soc.sas, Output: f_3_3702_km_ae_ge3_soc.rtf, Generated on: 20SEP2024 12:02,
Data Cutoff Date: 22SEP2023

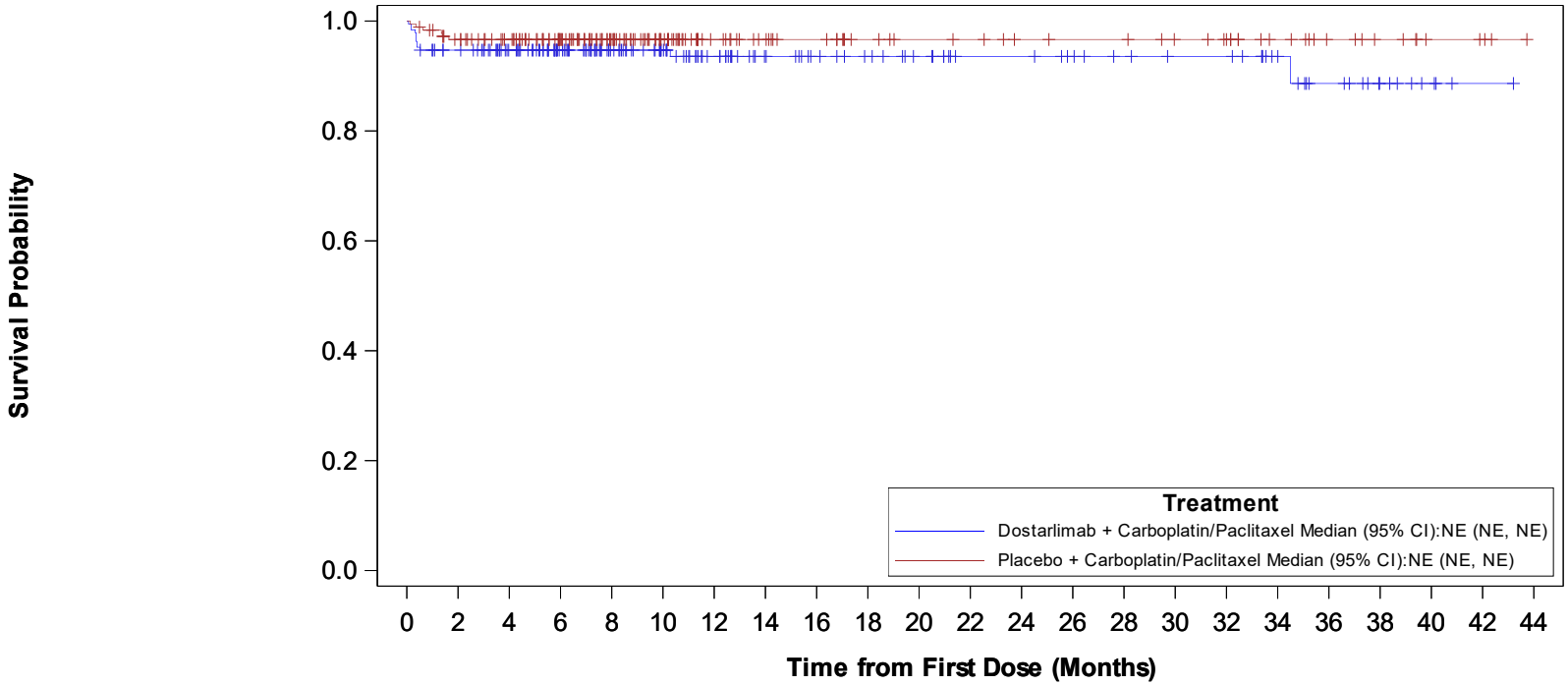
Figure 3.3702 Graph of Kaplan Meier Curves of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class
(Safety Analysis Set): MMRp/MSS Subjects
System Organ Class: General disorders and administration site conditions



Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_3702_km_ae_ge3_soc.sas, Output: f_3_3702_km_ae_ge3_soc.rtf, Generated on: 20SEP2024 12:02,
Data Cutoff Date: 22SEP2023

Figure 3.3702 Graph of Kaplan Meier Curves of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders



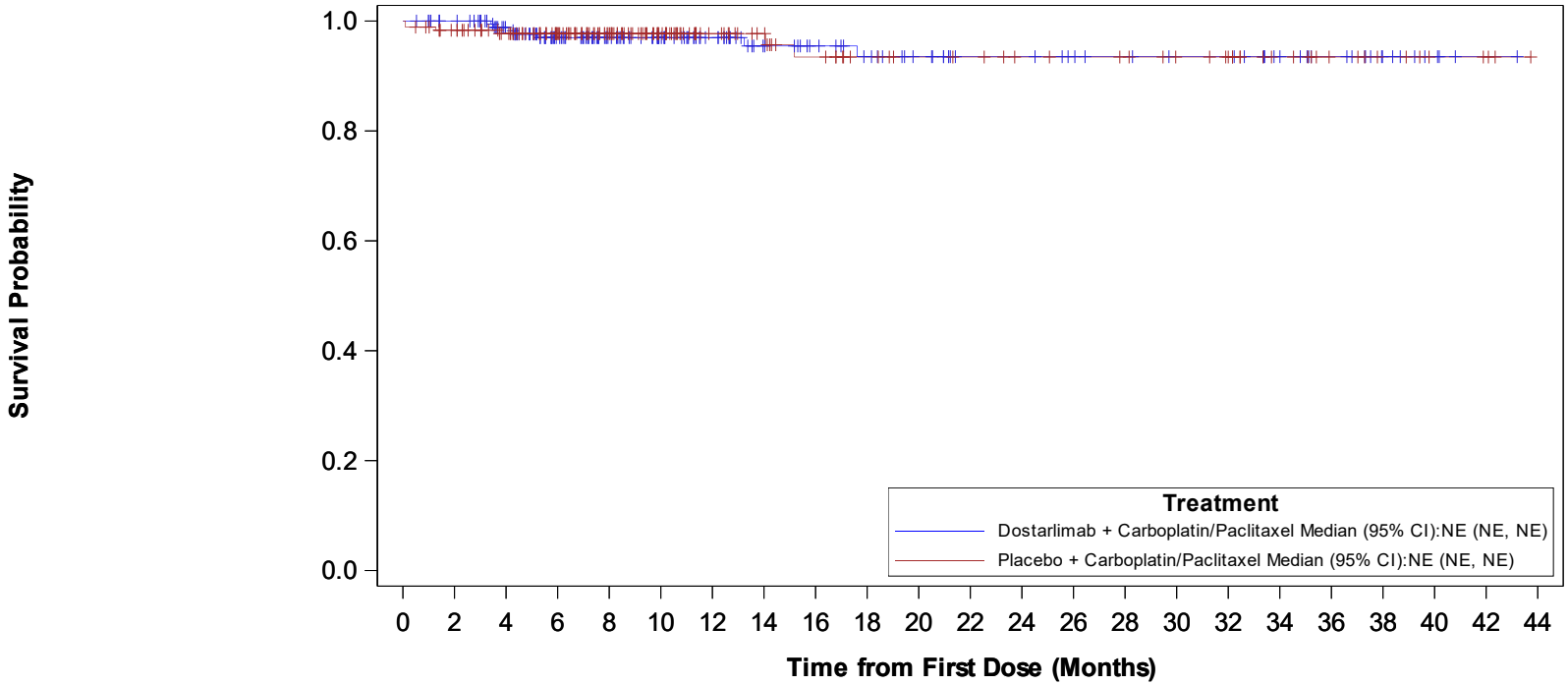
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	173(10)	156(10)	131(10)	105(10)	87(10)	71(11)	57(11)	51(11)	47(11)	42(11)	35(11)	35(11)	32(11)	29(11)	27(11)	27(11)	20(11)	14(12)	8(12)	4(12)	1(12)	0(12)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	168(6)	156(6)	131(6)	103(6)	78(6)	56(6)	48(6)	43(6)	36(6)	33(6)	32(6)	29(6)	28(6)	28(6)	25(6)	23(6)	16(6)	11(6)	8(6)	4(6)	3(6)	0(6)

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_3702_km_ae_ge3_soc.sas, Output: f_3_3702_km_ae_ge3_soc.rtf, Generated on: 20SEP2024 12:02,
Data Cutoff Date: 22SEP2023

Figure 3.3702 Graph of Kaplan Meier Curves of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Musculoskeletal and connective tissue disorders



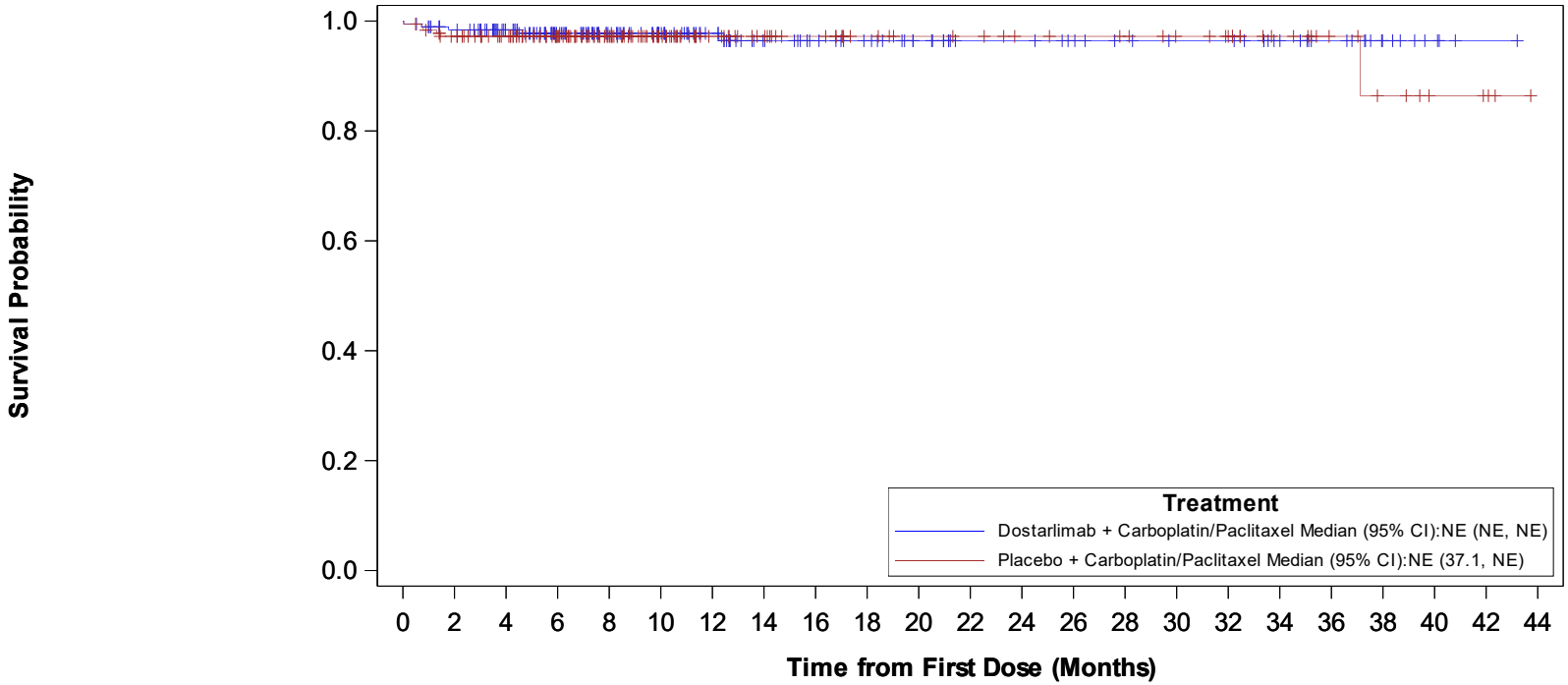
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	182(0)	164(2)	135(5)	110(5)	91(5)	75(5)	59(6)	53(6)	47(7)	41(7)	33(7)	33(7)	30(7)	28(7)	26(7)	26(7)	20(7)	15(7)	8(7)	4(7)	1(7)	0(7)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	171(3)	157(4)	132(4)	104(4)	79(4)	57(4)	49(4)	42(6)	36(6)	33(6)	32(6)	29(6)	28(6)	27(6)	24(6)	22(6)	15(6)	10(6)	7(6)	4(6)	3(6)	0(6)

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_3702_km_ae_ge3_soc.sas, Output: f_3_3702_km_ae_ge3_soc.rtf, Generated on: 20SEP2024 12:02,
Data Cutoff Date: 22SEP2023

Figure 3.3702 Graph of Kaplan Meier Curves of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Injury, poisoning and procedural complications

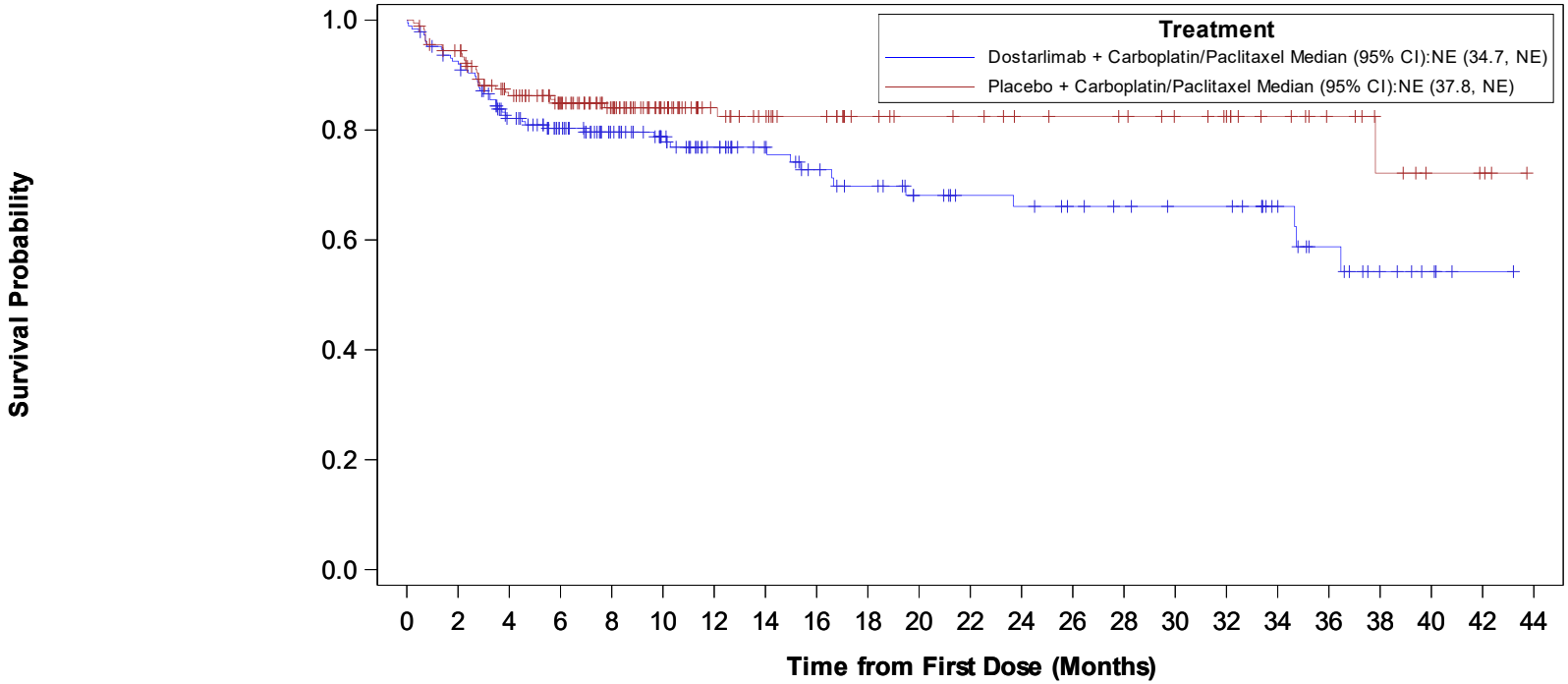


Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	179(3)	162(3)	135(4)	110(4)	91(4)	75(4)	60(5)	54(5)	49(5)	42(5)	34(5)	34(5)	31(5)	28(5)	26(5)	26(5)	20(5)	15(5)	8(5)	4(5)	1(5)	0(5)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	170(5)	157(5)	132(5)	103(5)	78(5)	57(5)	49(5)	43(5)	36(5)	33(5)	32(5)	29(5)	28(5)	27(5)	24(5)	22(5)	15(5)	10(5)	7(6)	4(6)	3(6)	0(6)

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
NE = Not Estimable.
Program: f_3_3702_km_ae_ge3_soc.sas, Output: f_3_3702_km_ae_ge3_soc.rtf, Generated on: 20SEP2024 12:02,
Data Cutoff Date: 22SEP2023

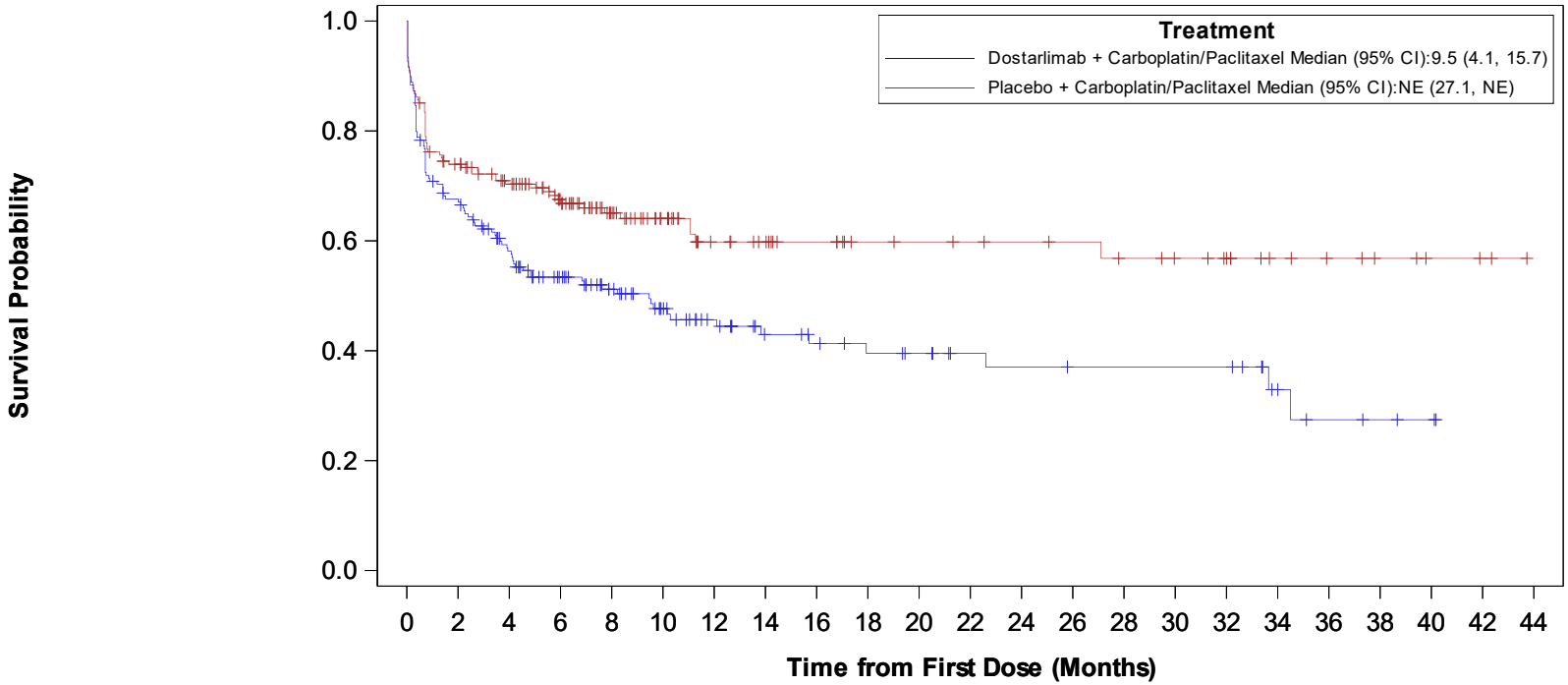
Figure 3.4102 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation (Safety Analysis Set): MMRp/MSS Subjects



NE = Not Estimable.
Program: f_3_4102_km_ae_disc.sas, Output: f_3_4102_km_ae_disc.rtf, Generated on: 23SEP2024 08:10,
Data Cutoff Date: 22SEP2023

Figure 3.4502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs



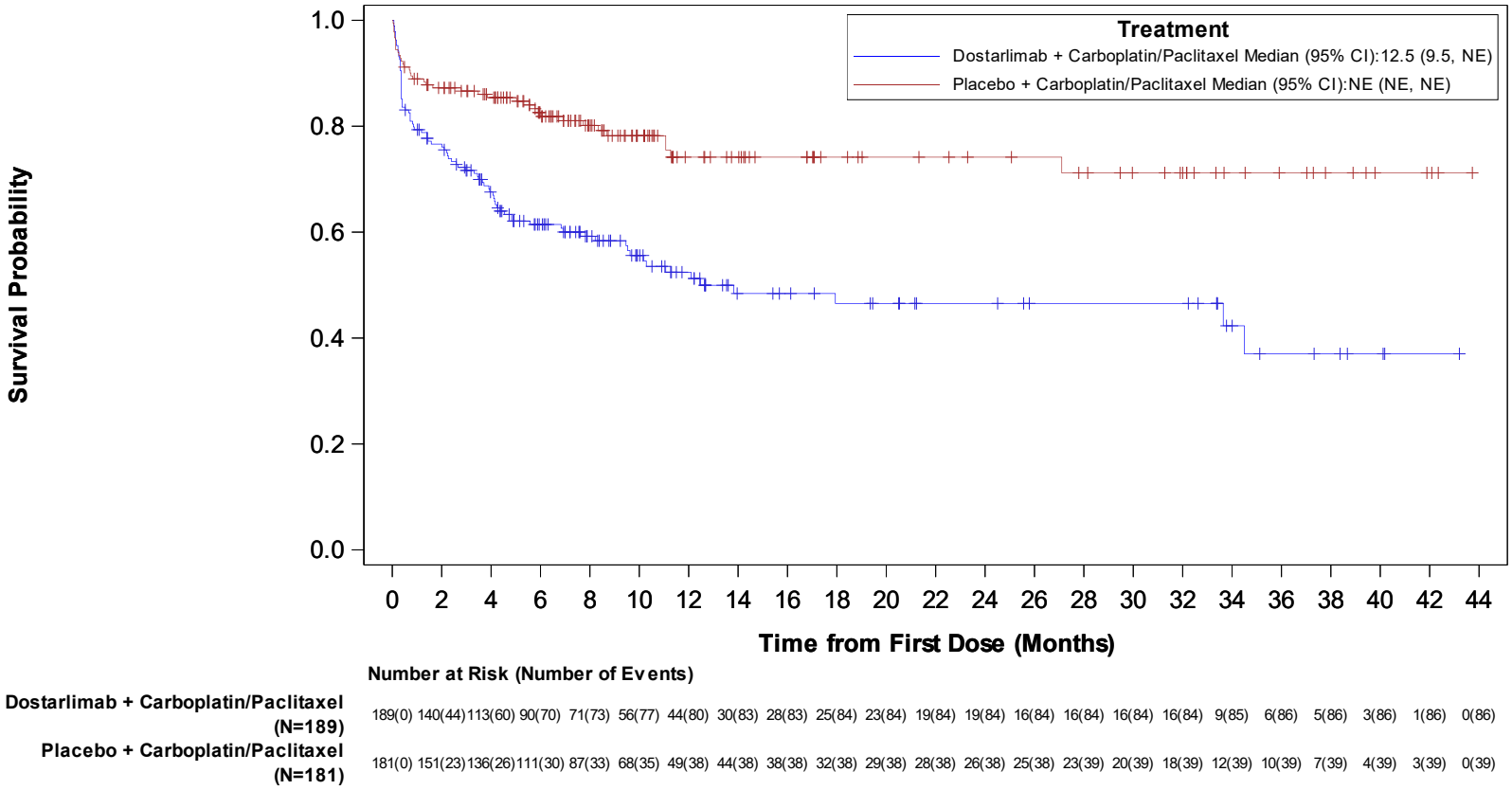
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	125(61)	100(78)	80(86)	63(89)	49(93)	38(95)	28(97)	25(98)	22(99)	20(99)	16(99)	15(100)	14(100)	14(100)	14(100)	14(100)	7(101)	4(102)	3(102)	2(102)	0(102)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	129(47)	113(53)	92(57)	68(60)	53(61)	38(64)	34(64)	29(64)	24(64)	23(64)	22(64)	21(64)	20(64)	18(65)	16(65)	14(65)	9(65)	7(65)	5(65)	3(65)	2(65)	0(65)

Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4502_km_irae.sas, Output: f_3_4502_km_irae.rtf, Generated on: 23SEP2024 11:21,
Data Cutoff Date: 22SEP2023

Figure 3.4502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

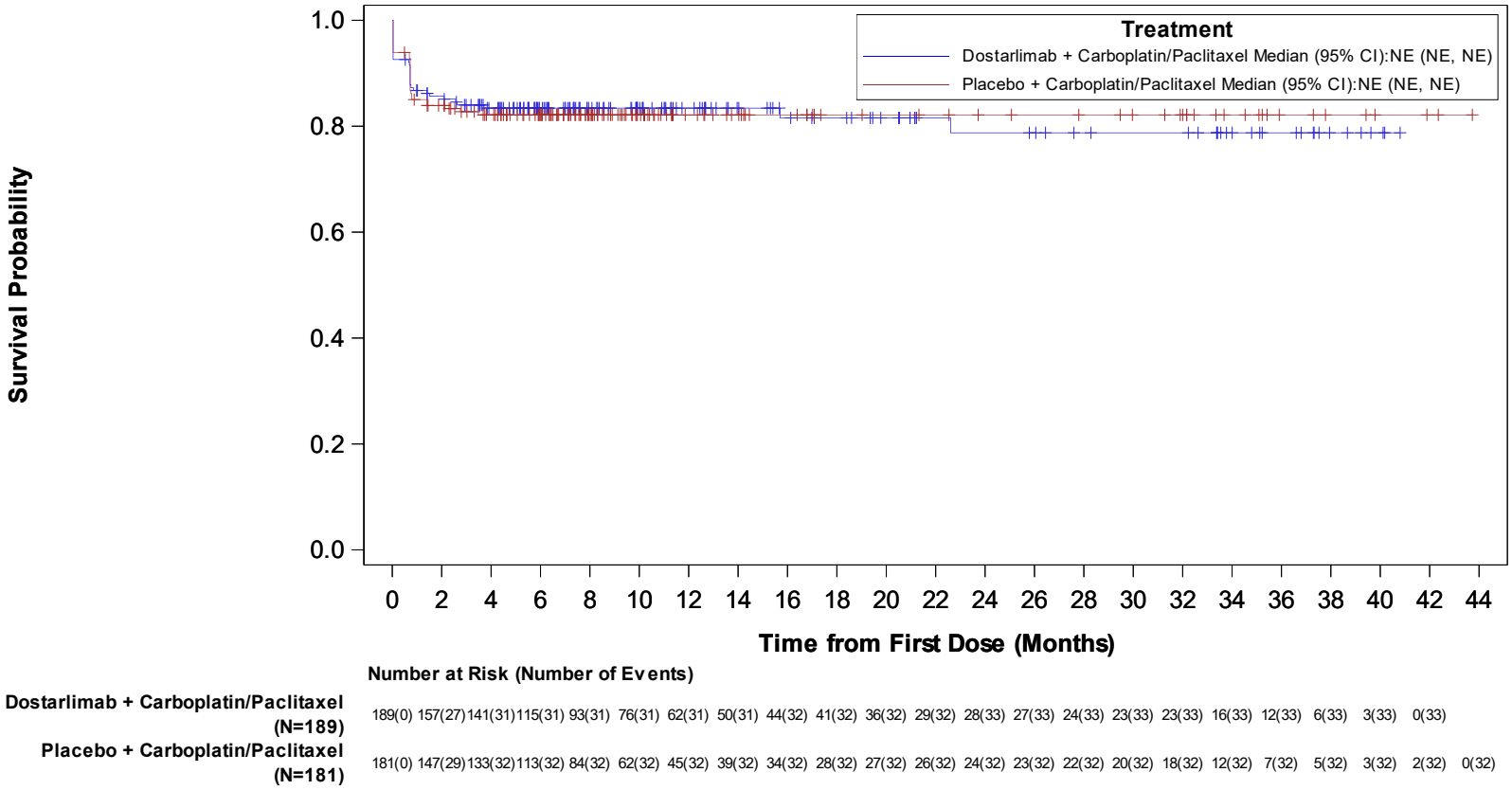
irAE Category: Non-hypersensitivity



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4502_km_irae.sas, Output: f_3_4502_km_irae.rtf, Generated on: 23SEP2024 11:21,
Data Cutoff Date: 22SEP2023

Figure 3.4502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

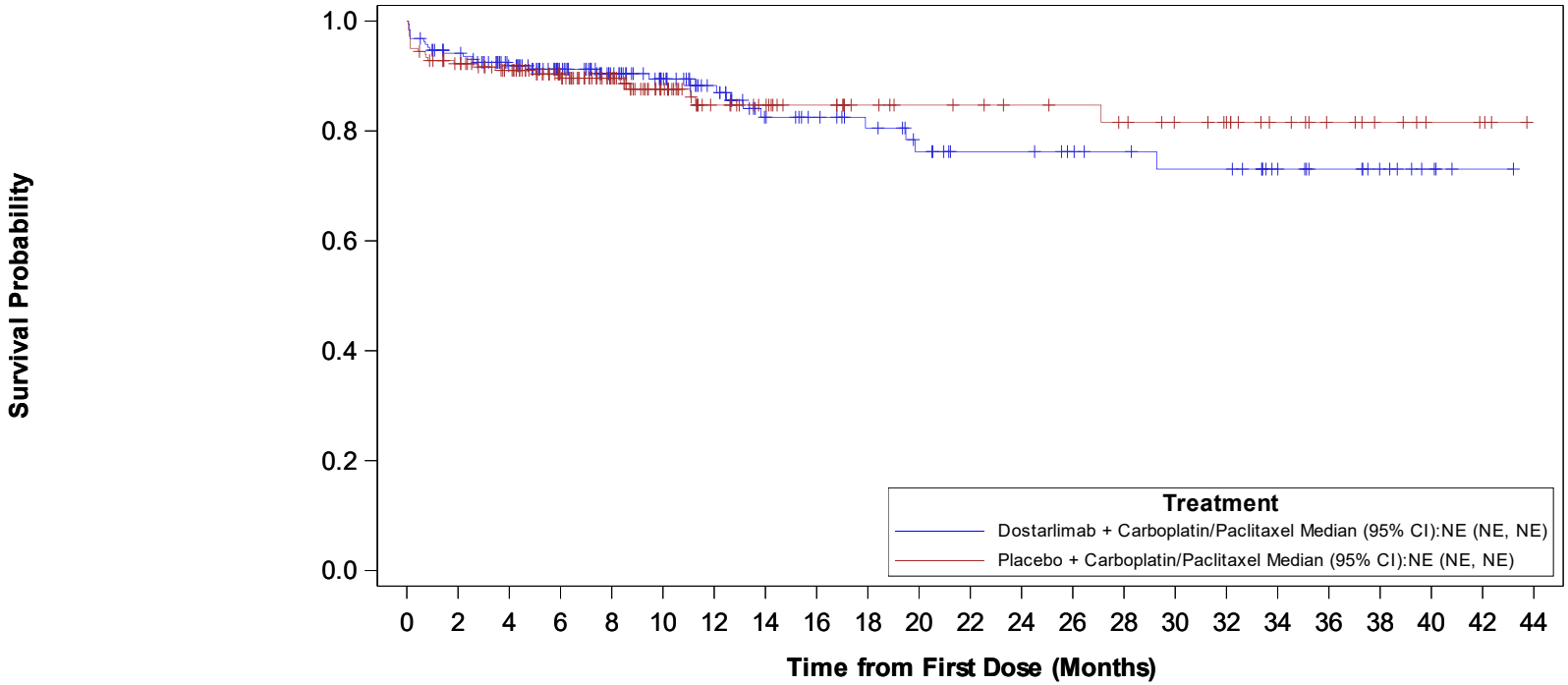
irAE Category: Hypersensitivity



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4502_km_irae.sas, Output: f_3_4502_km_irae.rtf, Generated on: 23SEP2024 11:21,
Data Cutoff Date: 22SEP2023

Figure 3.4502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal



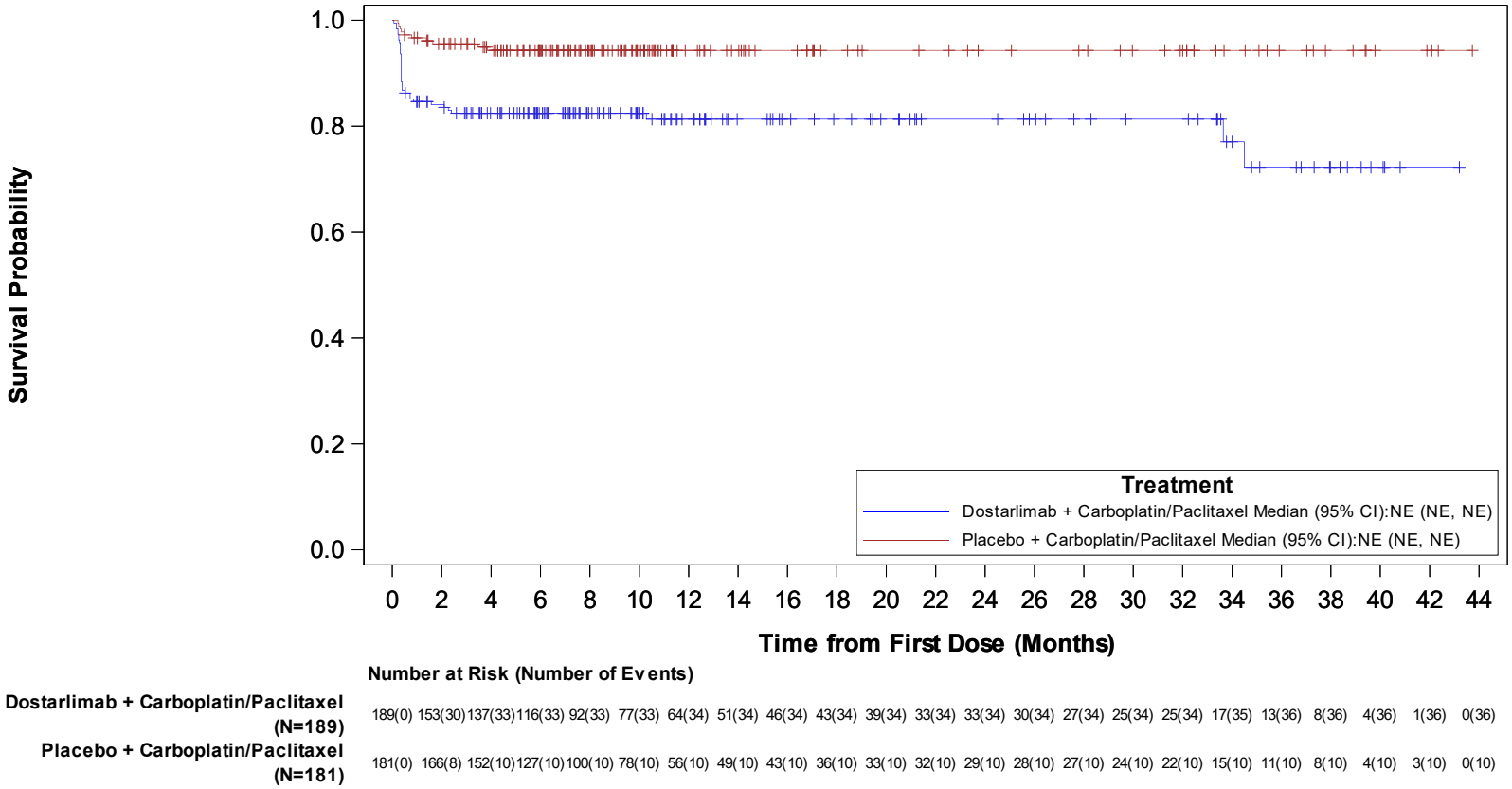
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	171(11)	151(15)	126(16)	103(17)	84(18)	68(19)	51(23)	46(23)	41(24)	35(26)	30(26)	30(26)	27(26)	25(26)	23(27)	23(27)	16(27)	12(27)	8(27)	4(27)	1(27)	0(27)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	160(14)	146(16)	121(17)	95(18)	72(20)	52(22)	46(22)	40(22)	34(22)	31(22)	30(22)	28(22)	27(22)	25(23)	22(23)	20(23)	14(23)	10(23)	7(23)	4(23)	3(23)	0(23)

Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4502_km_irae.sas, Output: f_3_4502_km_irae.rtf, Generated on: 23SEP2024 11:21,
Data Cutoff Date: 22SEP2023

Figure 3.4502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

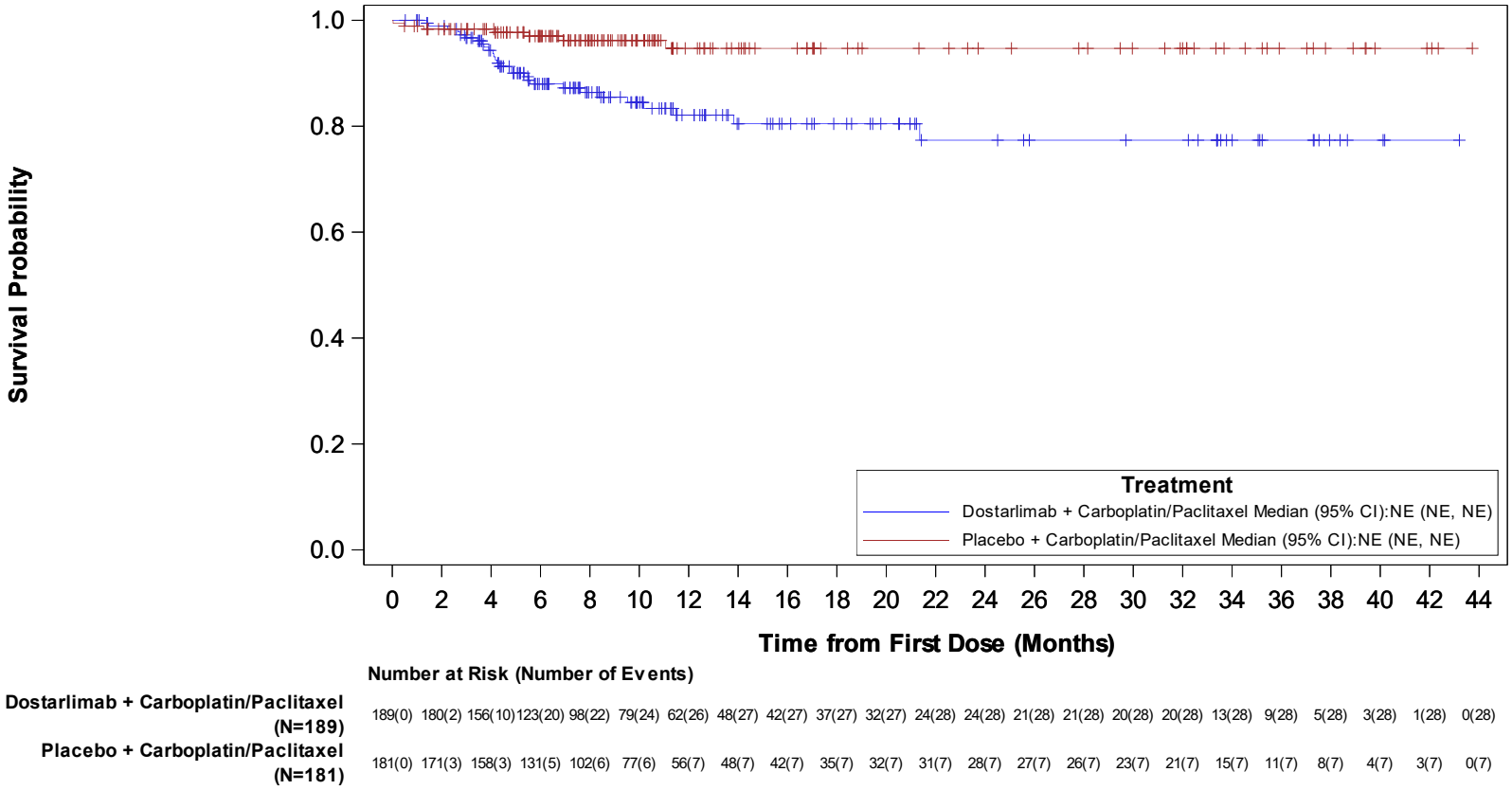
irAE Category: Immune-mediated Skin Adverse Reactions



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4502_km_irae.sas, Output: f_3_4502_km_irae.rtf, Generated on: 23SEP2024 11:21,
Data Cutoff Date: 22SEP2023

Figure 3.4502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

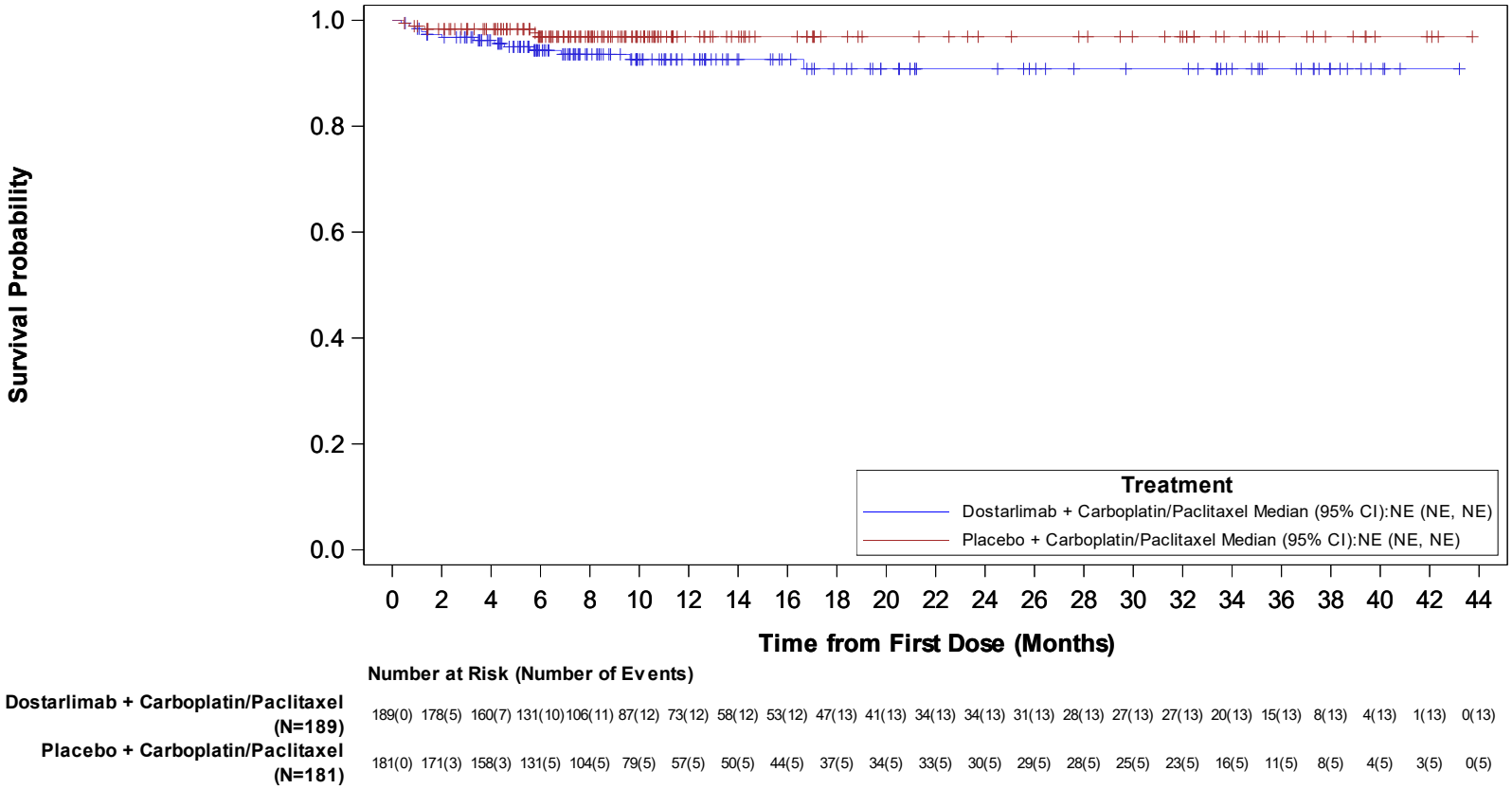
irAE Category: Immune-mediated Endocrinopathies



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4502_km_irae.sas, Output: f_3_4502_km_irae.rtf, Generated on: 23SEP2024 11:21,
Data Cutoff Date: 22SEP2023

Figure 3.4502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

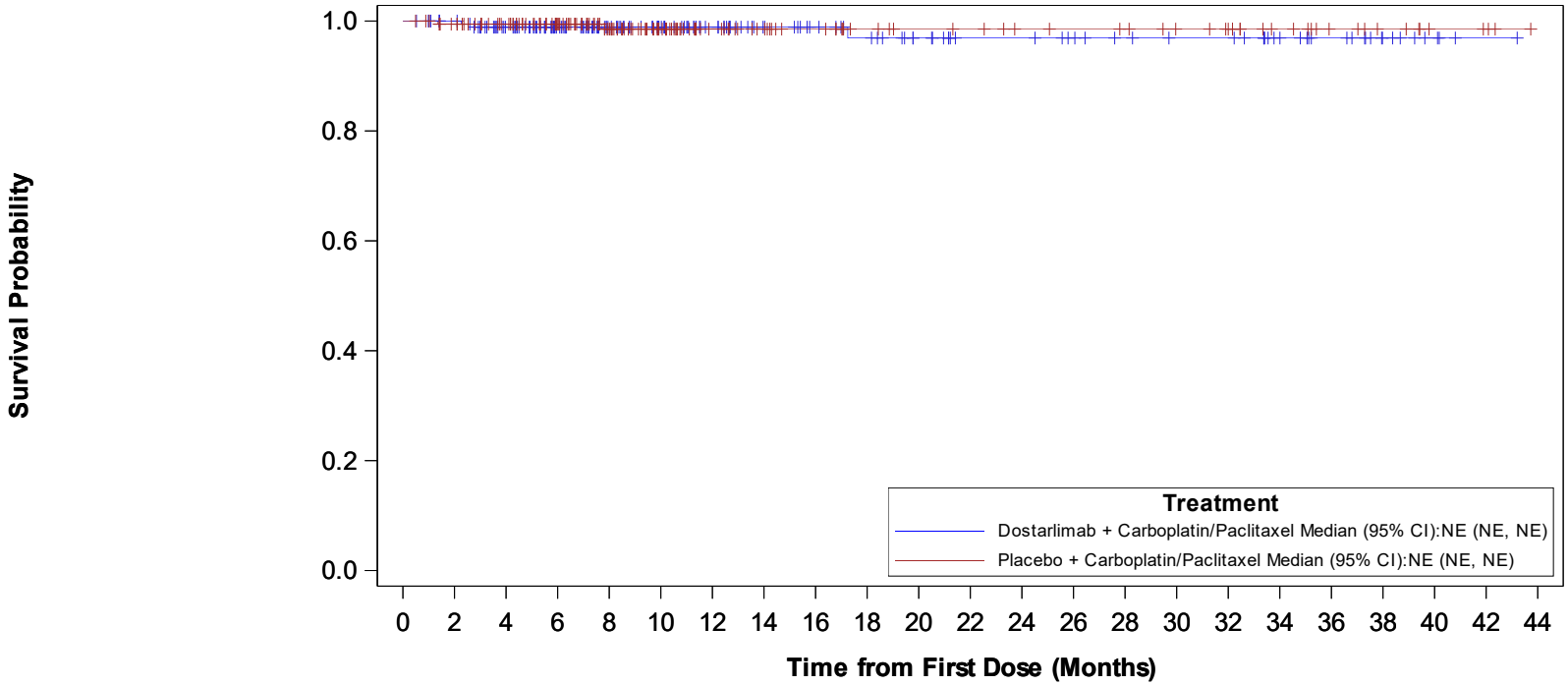
irAE Category: Immune-mediated Hepatic



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4502_km_irae.sas, Output: f_3_4502_km_irae.rtf, Generated on: 23SEP2024 11:21,
Data Cutoff Date: 22SEP2023

Figure 3.4502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal



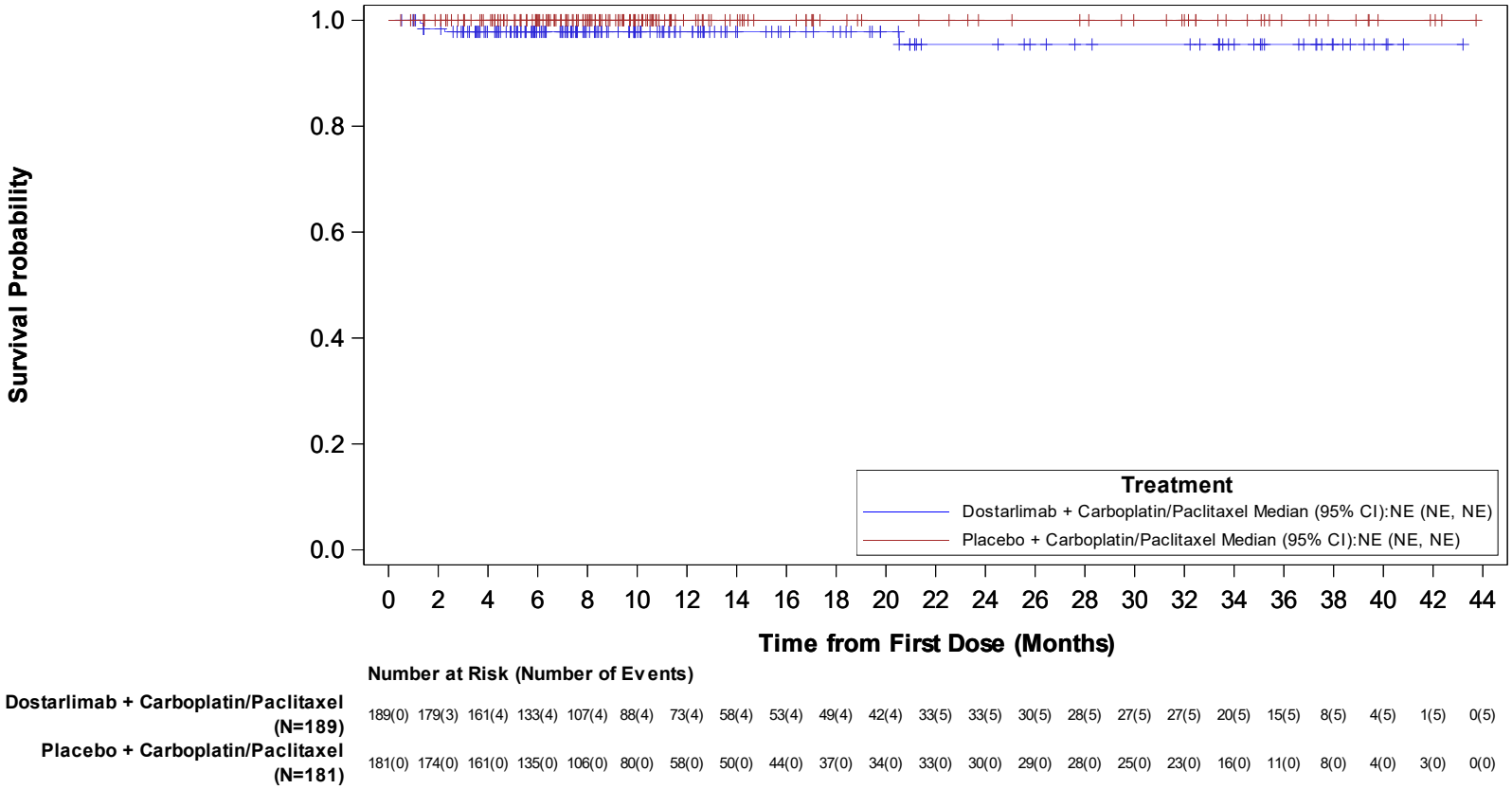
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	182(0)	164(2)	136(2)	110(2)	91(2)	75(2)	60(2)	54(2)	49(3)	42(3)	35(3)	35(3)	32(3)	29(3)	27(3)	27(3)	20(3)	15(3)	8(3)	4(3)	1(3)	0(3)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	173(1)	160(1)	134(1)	105(2)	80(2)	58(2)	50(2)	44(2)	37(2)	34(2)	33(2)	30(2)	29(2)	28(2)	25(2)	23(2)	16(2)	11(2)	8(2)	4(2)	3(2)	0(2)

Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4502_km_irae.sas, Output: f_3_4502_km_irae.rtf, Generated on: 23SEP2024 11:21,
Data Cutoff Date: 22SEP2023

Figure 3.4502 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

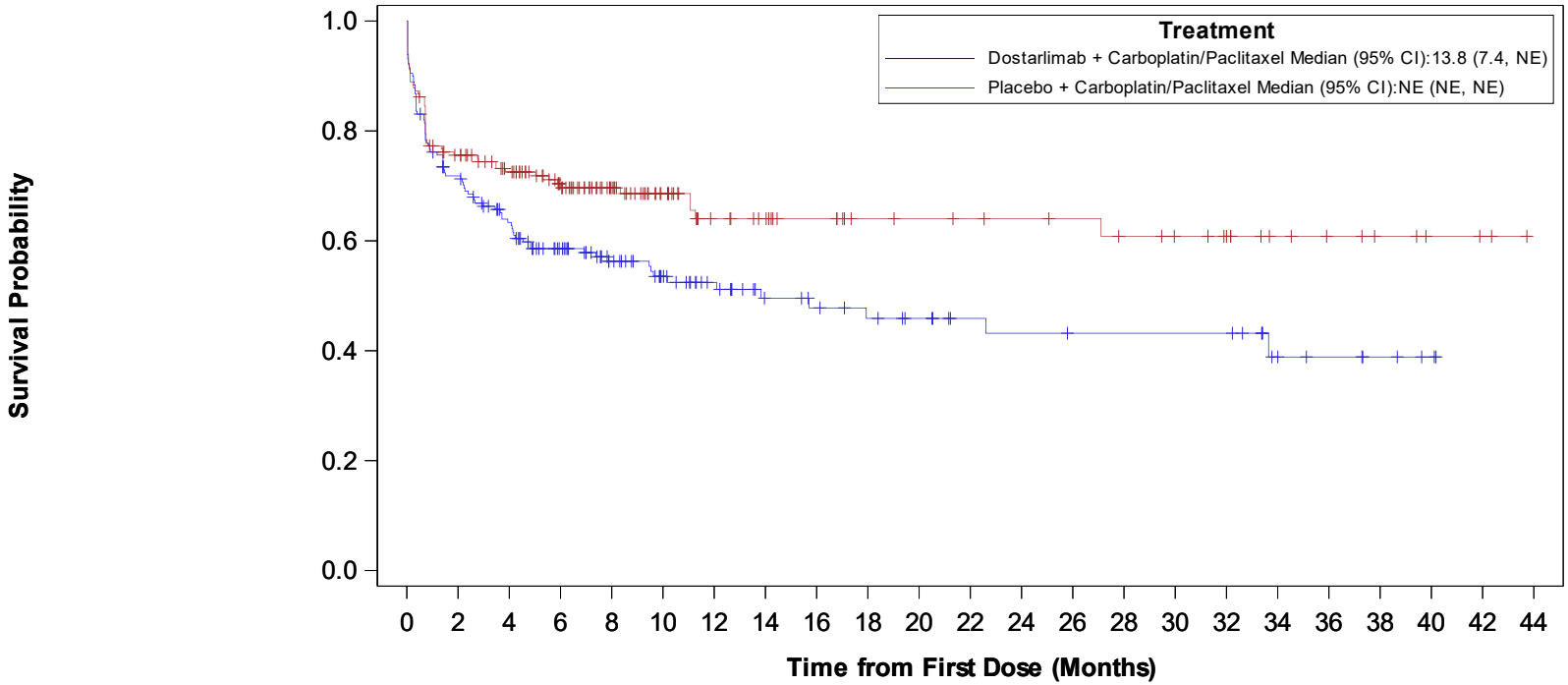
irAE Category: Immune-mediated Pulmonary



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4502_km_irae.sas, Output: f_3_4502_km_irae.rtf, Generated on: 23SEP2024 11:21,
Data Cutoff Date: 22SEP2023

Figure 3.4902 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-related Adverse Events of Grade <=2 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs



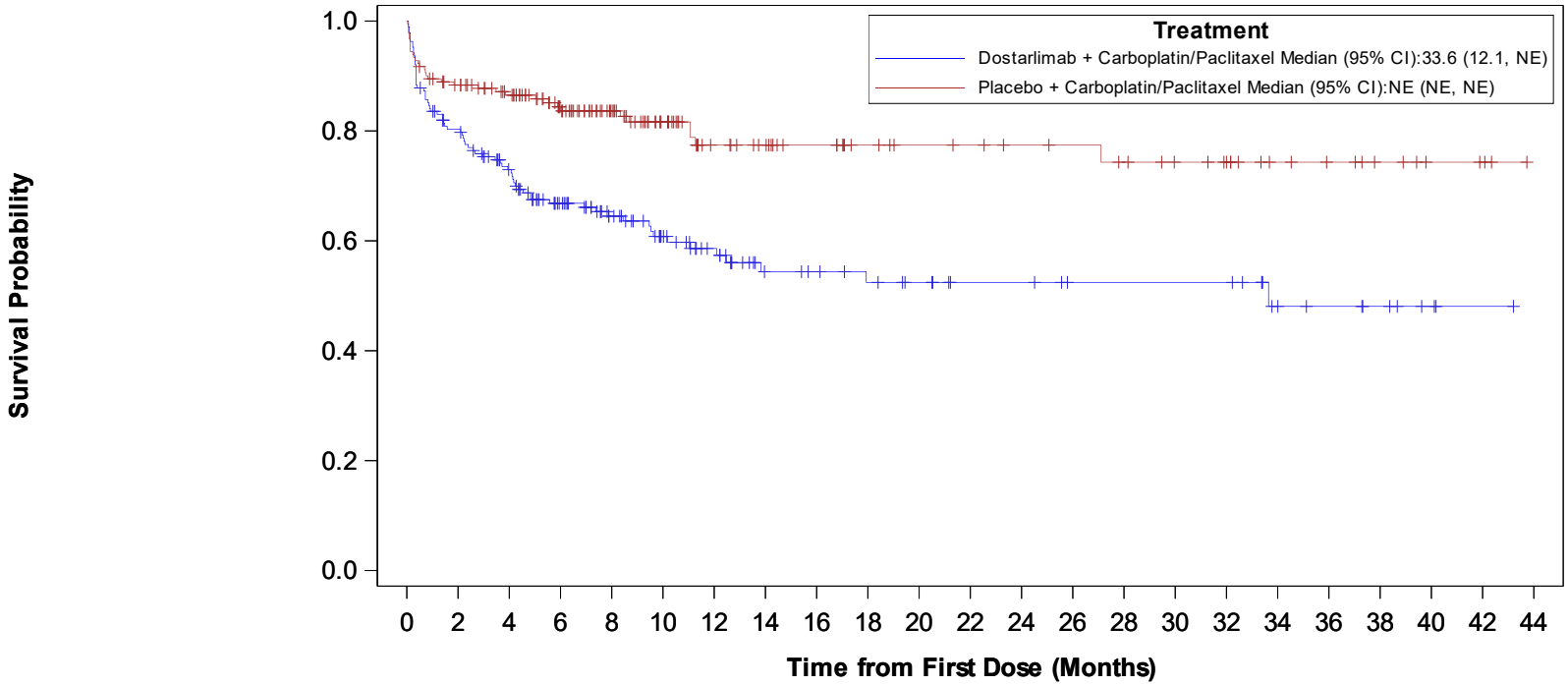
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	131(53)	108(68)	86(76)	67(79)	52(82)	41(83)	30(85)	27(86)	24(87)	21(87)	17(87)	16(88)	15(88)	15(88)	15(88)	15(88)	8(89)	6(89)	4(89)	2(89)	0(89)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	131(44)	115(49)	93(52)	71(53)	53(54)	38(57)	34(57)	29(57)	24(57)	23(57)	22(57)	21(57)	20(57)	18(58)	16(58)	14(58)	9(58)	7(58)	5(58)	3(58)	2(58)	0(58)

Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4902_km_irae_le2.sas, Output: f_3_4902_km_irae_le2.rtf, Generated on: 19SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Figure 3.4902 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-related Adverse Events of Grade <=2 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity



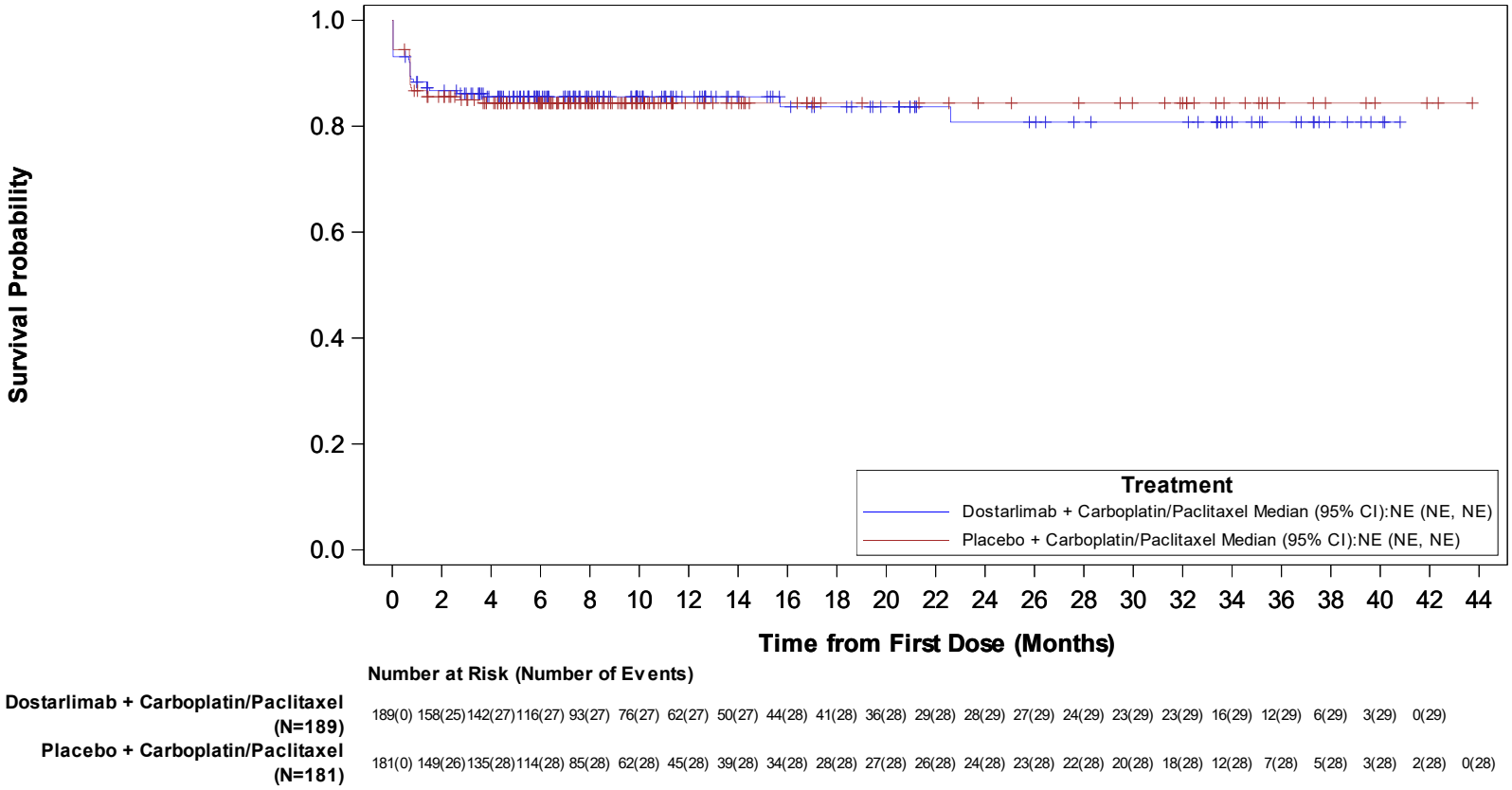
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	189(0)	146(37)	122(50)	96(60)	76(63)	59(67)	47(69)	32(72)	30(72)	27(73)	24(73)	20(73)	20(73)	17(73)	17(73)	17(73)	17(73)	10(74)	8(74)	6(74)	3(74)	1(74)	0(74)
Placebo + Carboplatin/Paclitaxel (N=181)	181(0)	153(21)	138(24)	111(27)	89(28)	68(30)	49(33)	44(33)	38(33)	32(33)	29(33)	28(33)	26(33)	25(33)	23(34)	20(34)	18(34)	12(34)	10(34)	7(34)	4(34)	3(34)	0(34)

Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4902_km_irae_le2.sas, Output: f_3_4902_km_irae_le2.rtf, Generated on: 19SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Figure 3.4902 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-related Adverse Events of Grade <=2 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

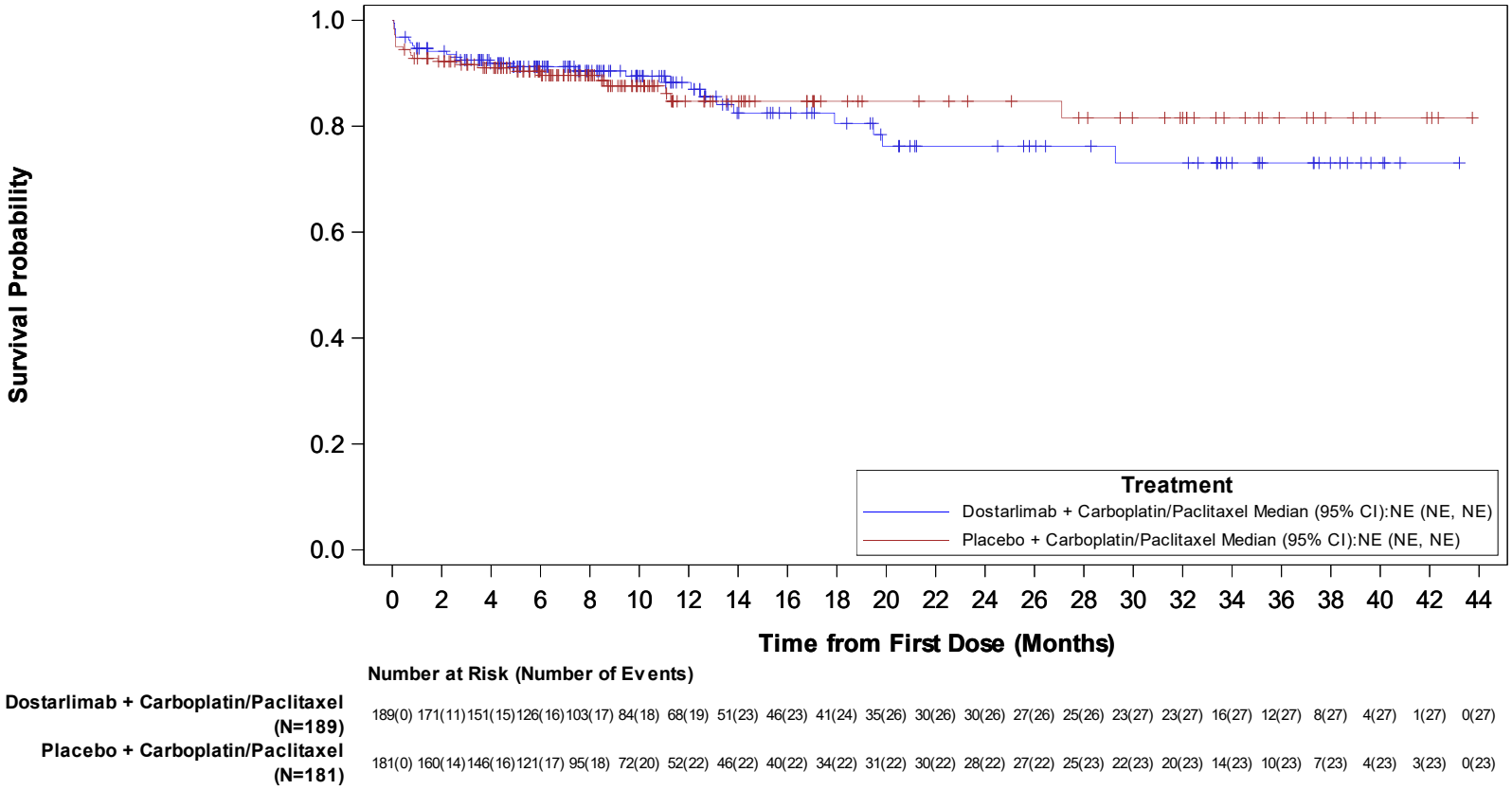
irAE Category: Hypersensitivity



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4902_km_irae_le2.sas, Output: f_3_4902_km_irae_le2.rtf, Generated on: 19SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Figure 3.4902 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-related Adverse Events of Grade <=2 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

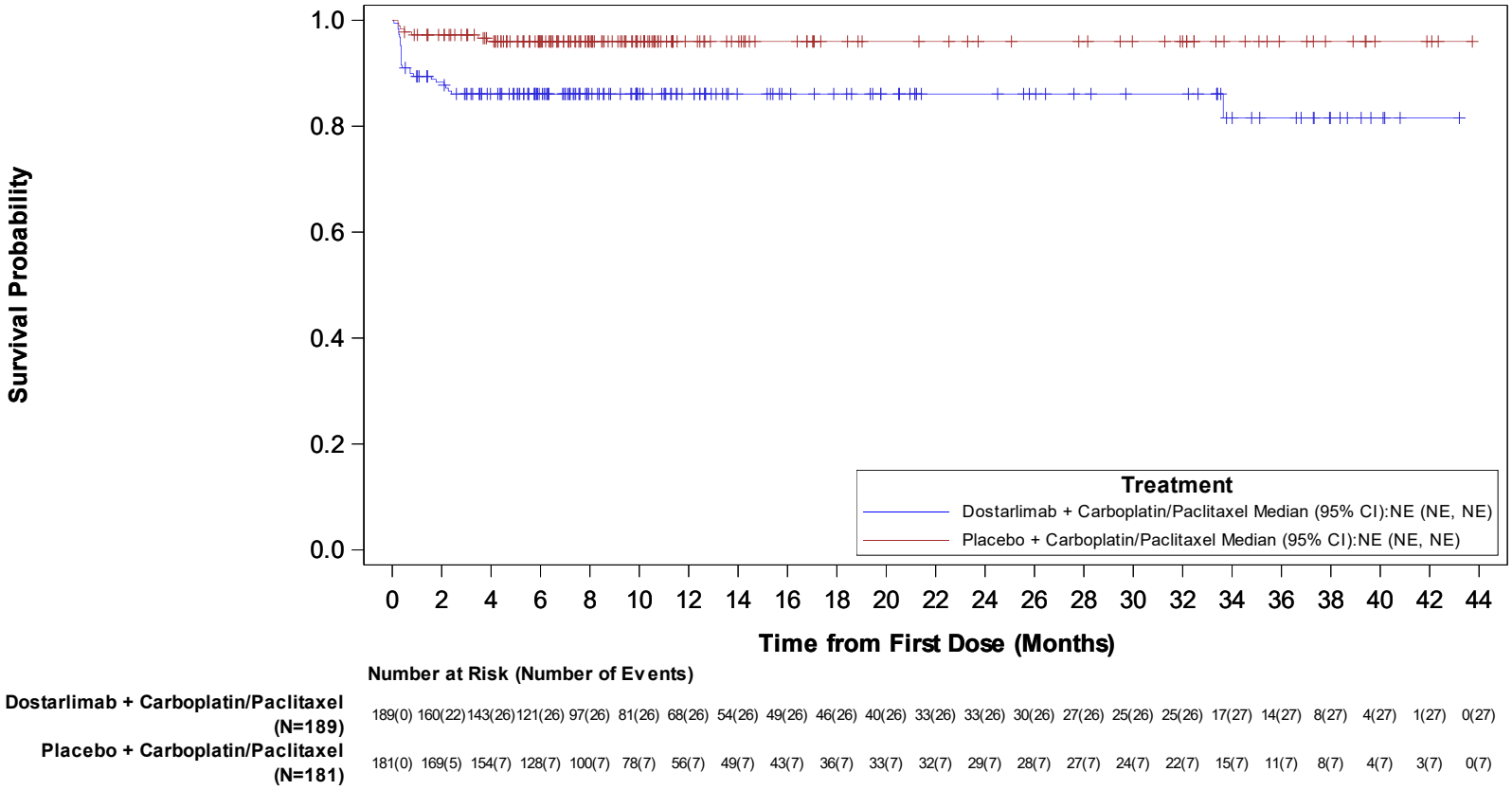
irAE Category: Immune-mediated Musculoskeletal



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4902_km_irae_le2.sas, Output: f_3_4902_km_irae_le2.rtf, Generated on: 19SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Figure 3.4902 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-related Adverse Events of Grade <=2 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

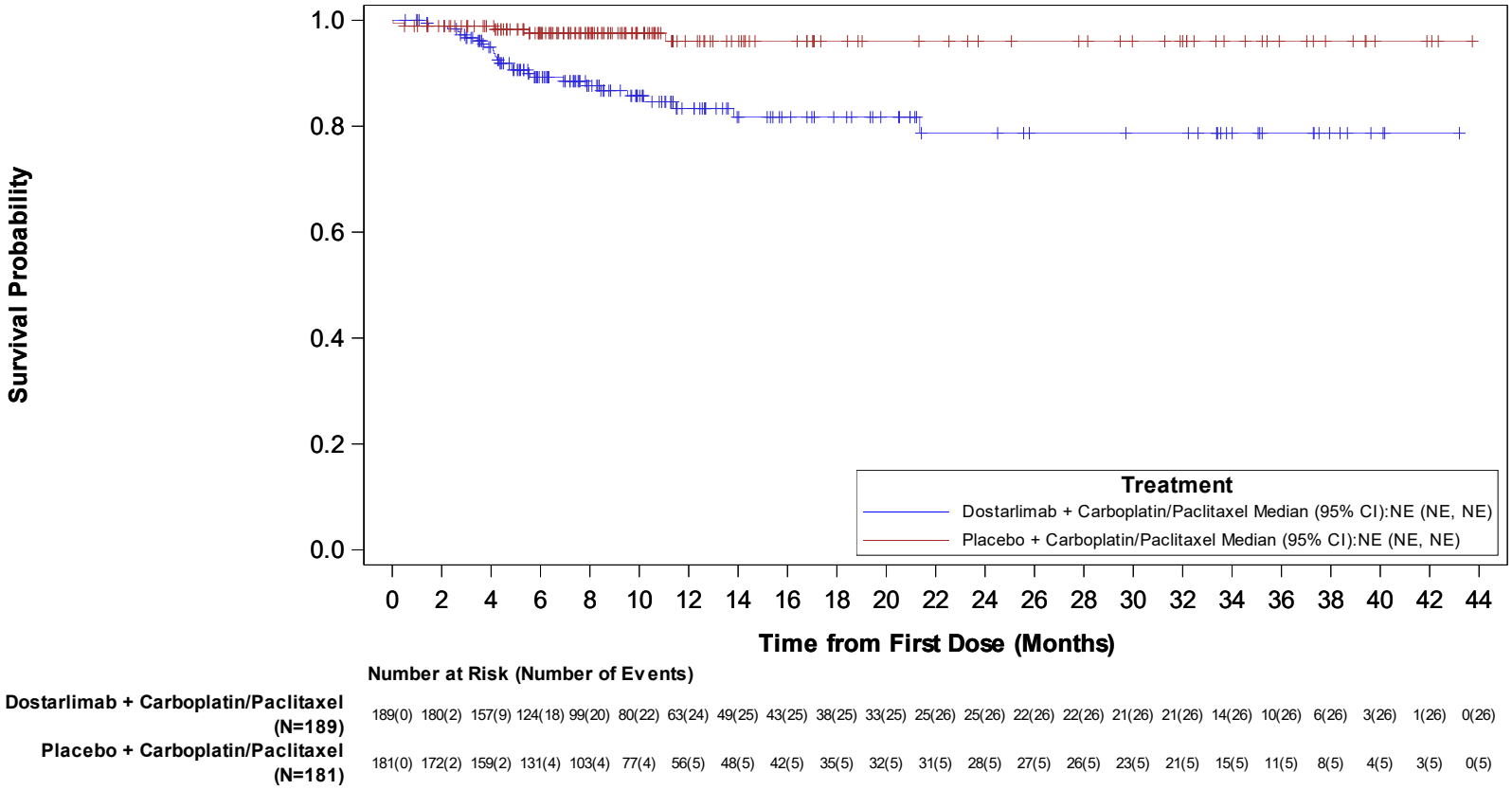
irAE Category: Immune-mediated Skin Adverse Reactions



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4902_km_irae_le2.sas, Output: f_3_4902_km_irae_le2.rtf, Generated on: 19SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Figure 3.4902 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-related Adverse Events of Grade <=2 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

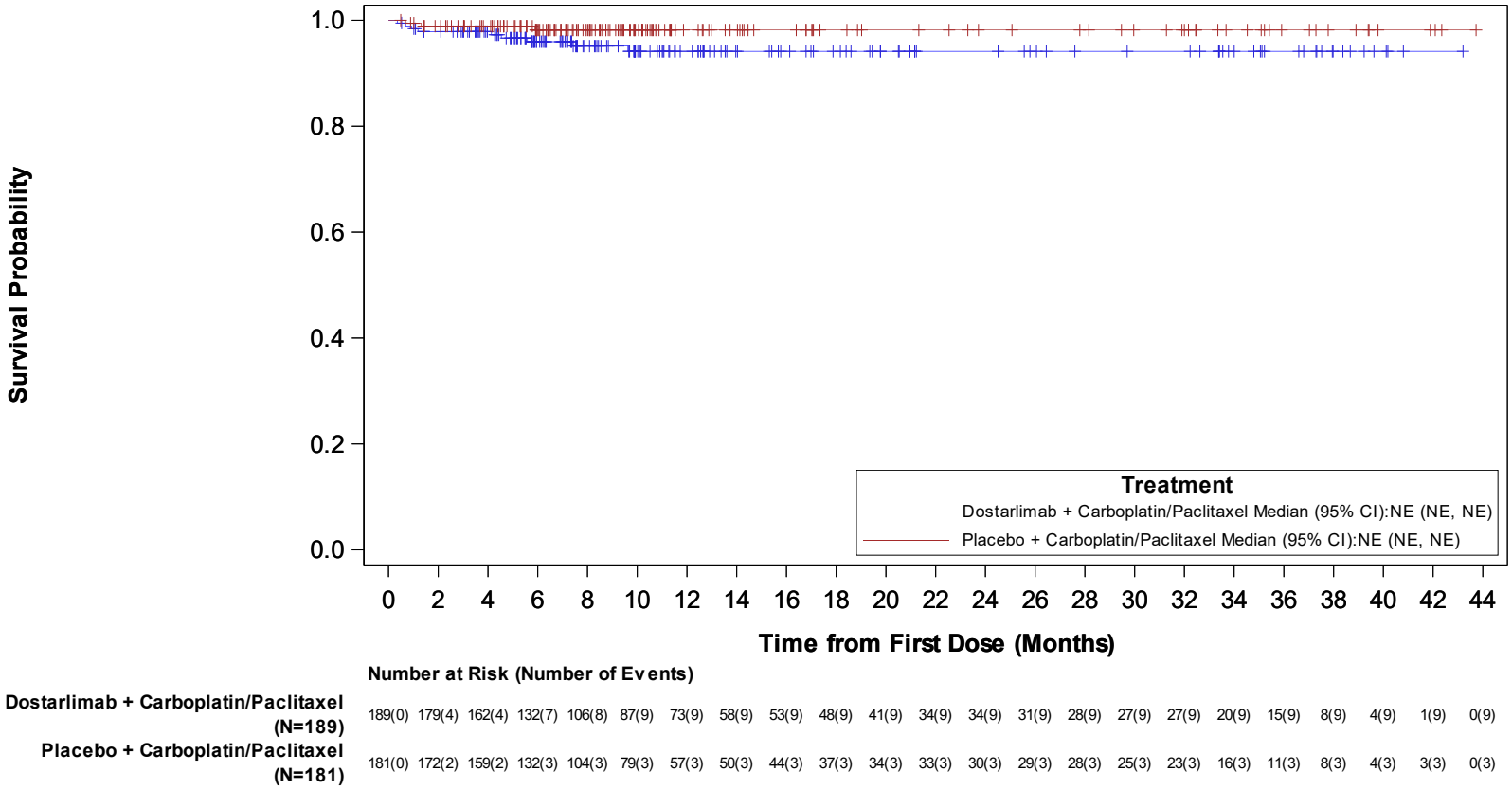
irAE Category: Immune-mediated Endocrinopathies



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4902_km_irae_le2.sas, Output: f_3_4902_km_irae_le2.rtf, Generated on: 19SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Figure 3.4902 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-related Adverse Events of Grade <=2 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

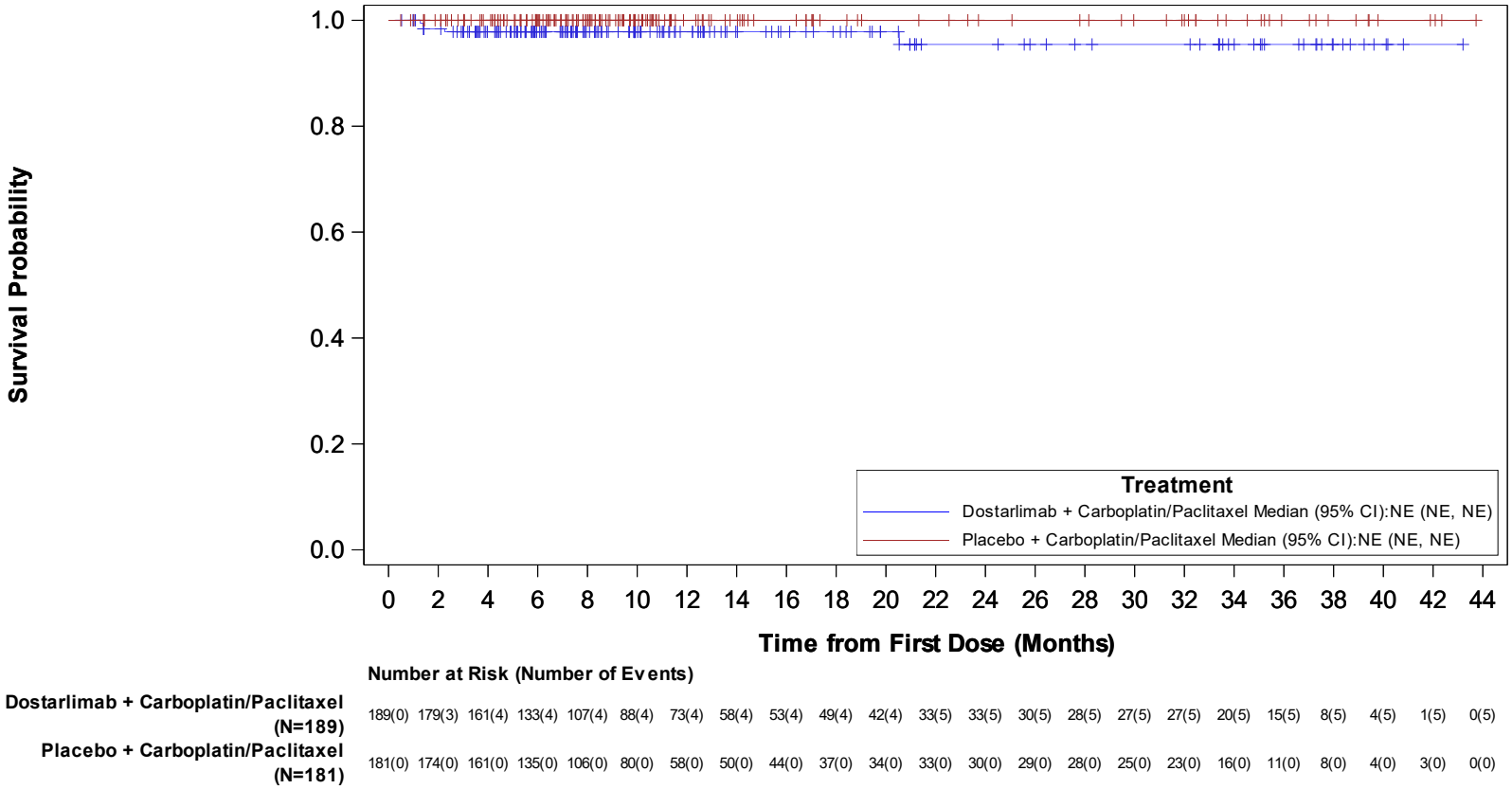
irAE Category: Immune-mediated Hepatic



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4902_km_irae_le2.sas, Output: f_3_4902_km_irae_le2.rtf, Generated on: 19SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Figure 3.4902 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-related Adverse Events of Grade <=2 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

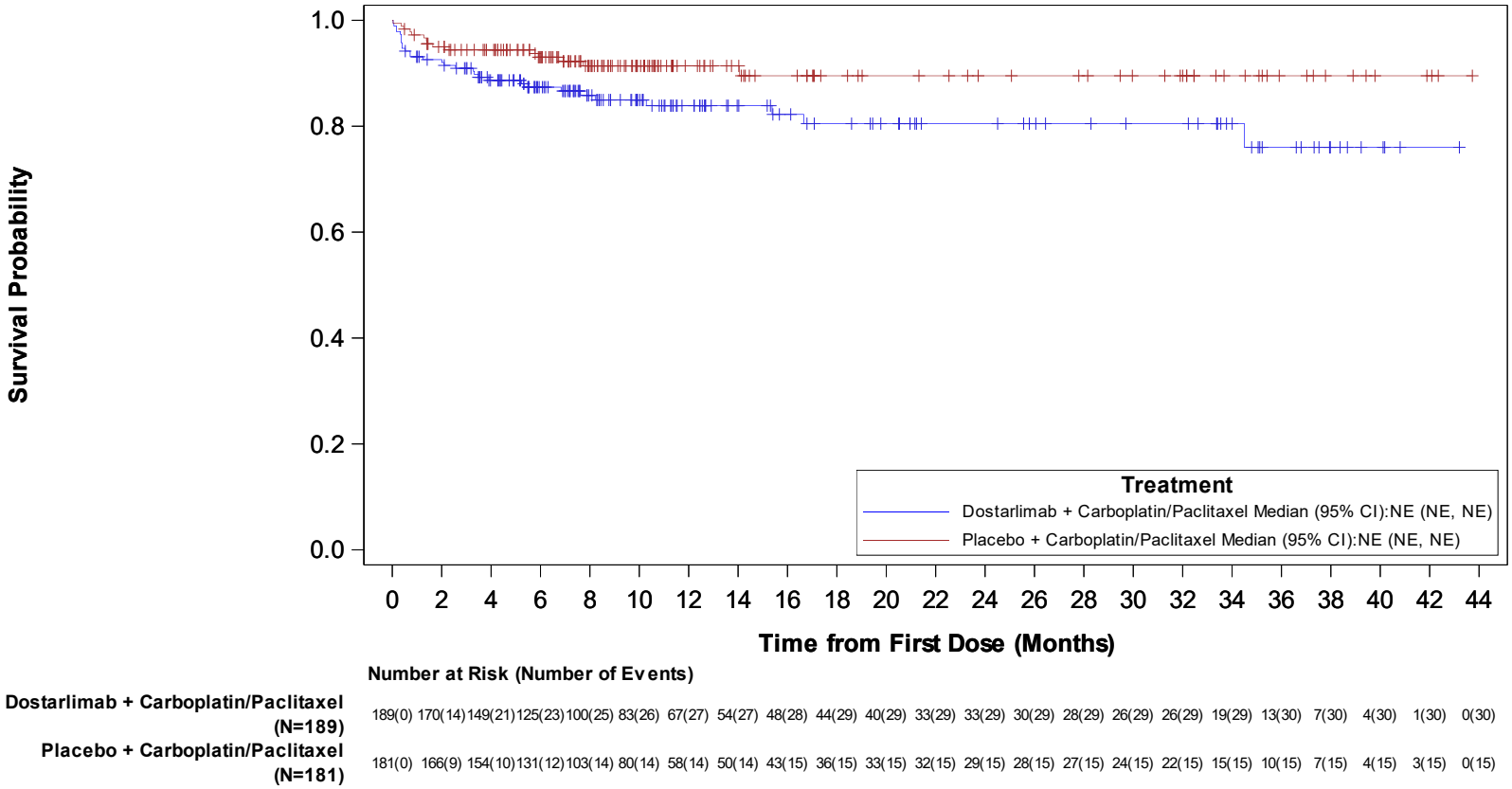
irAE Category: Immune-mediated Pulmonary



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_4902_km_irae_le2.sas, Output: f_3_4902_km_irae_le2.rtf, Generated on: 19SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Figure 3.5302 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

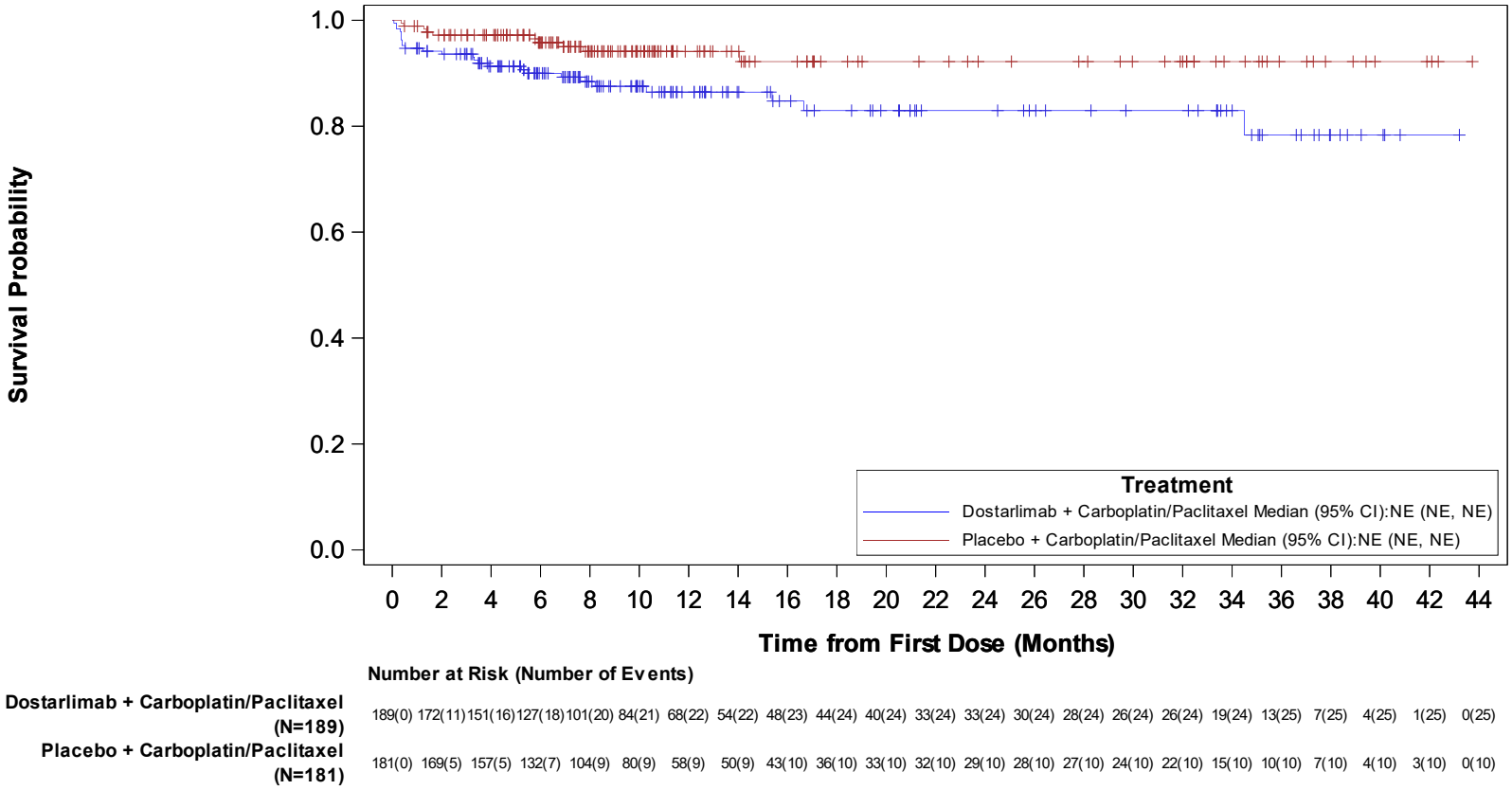
irAE Category: All irAEs



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_5302_km_irae_ge3.sas, Output: f_3_5302_km_irae_ge3.rtf, Generated on: 20SEP2024 14:20,
Data Cutoff Date: 22SEP2023

Figure 3.5302 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

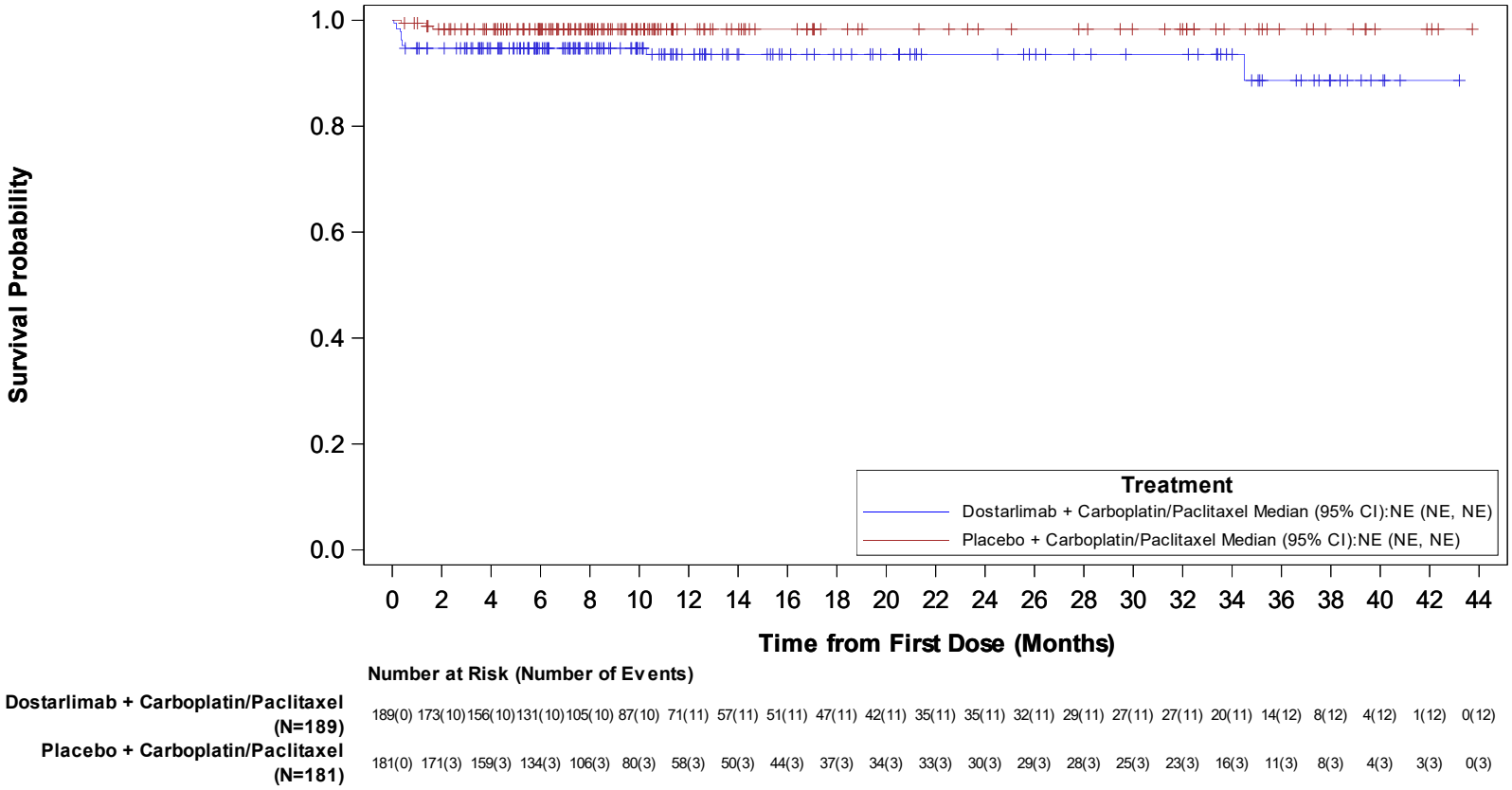
irAE Category: Non-hypersensitivity



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_5302_km_irae_ge3.sas, Output: f_3_5302_km_irae_ge3.rtf, Generated on: 20SEP2024 14:20,
Data Cutoff Date: 22SEP2023

Figure 3.5302 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

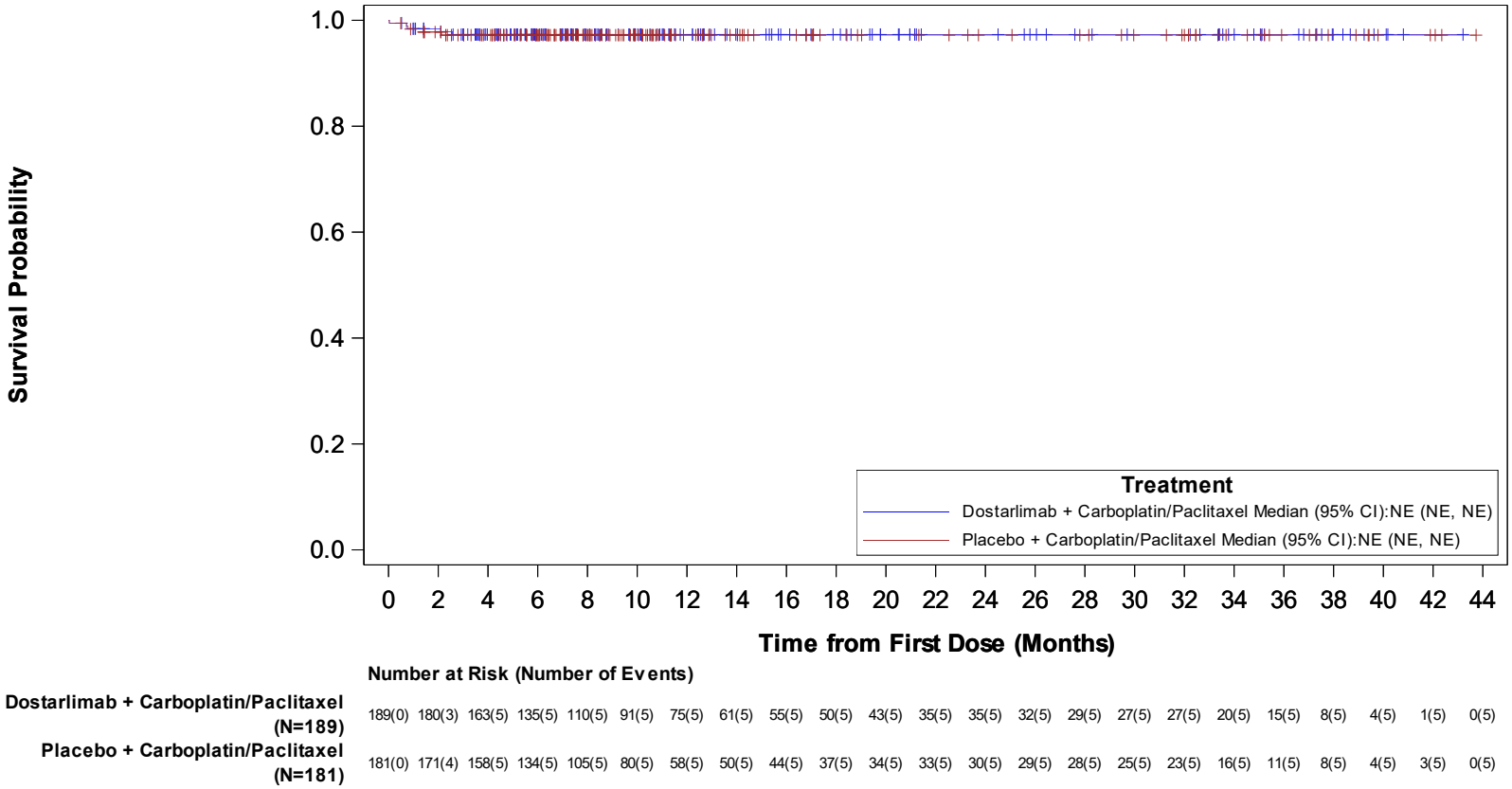
irAE Category: Immune-mediated Skin Adverse Reactions



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_5302_km_irae_ge3.sas, Output: f_3_5302_km_irae_ge3.rtf, Generated on: 20SEP2024 14:20,
Data Cutoff Date: 22SEP2023

Figure 3.5302 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

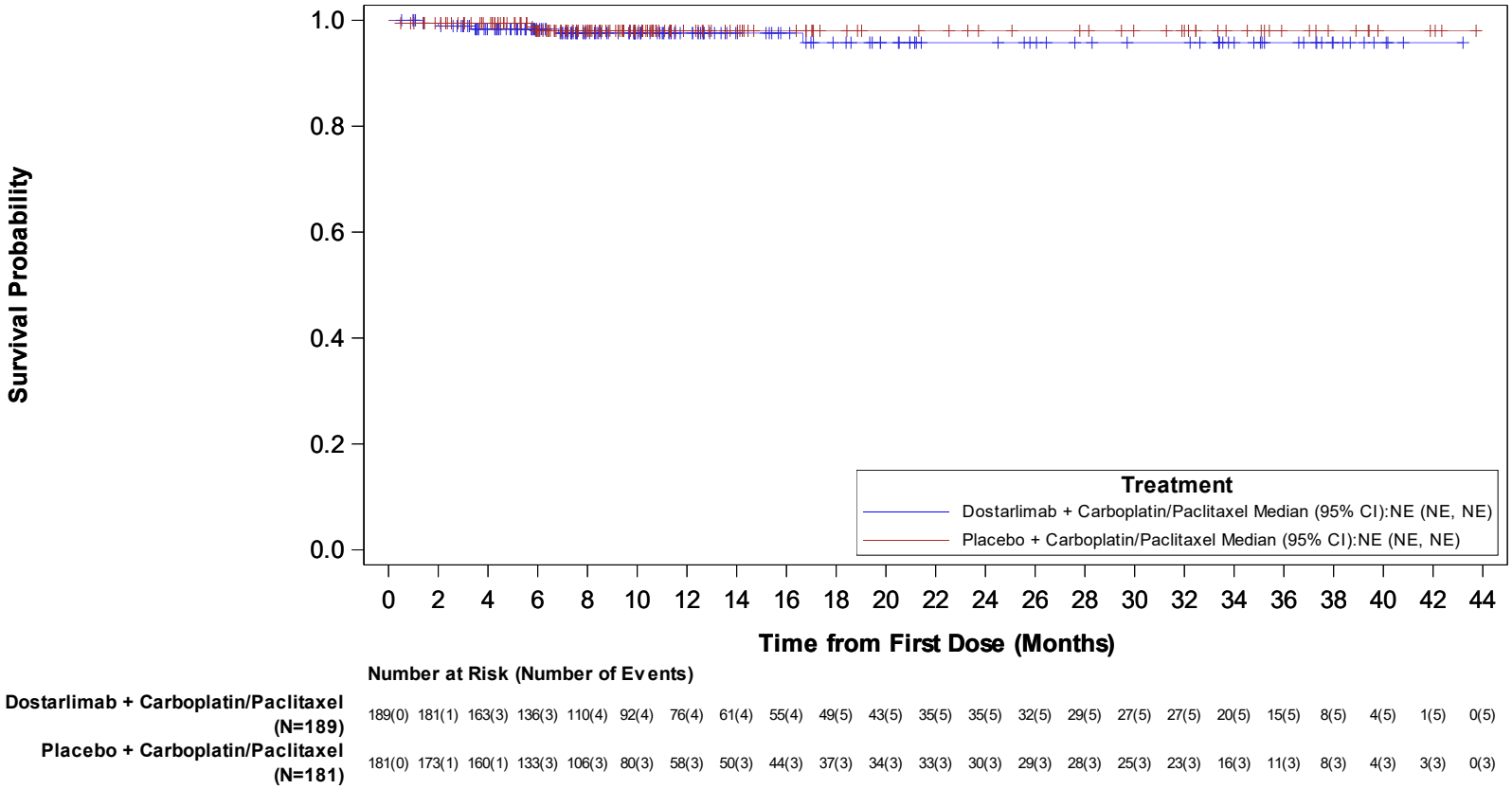
irAE Category: Hypersensitivity



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_5302_km_irae_ge3.sas, Output: f_3_5302_km_irae_ge3.rtf, Generated on: 20SEP2024 14:20,
Data Cutoff Date: 22SEP2023

Figure 3.5302 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

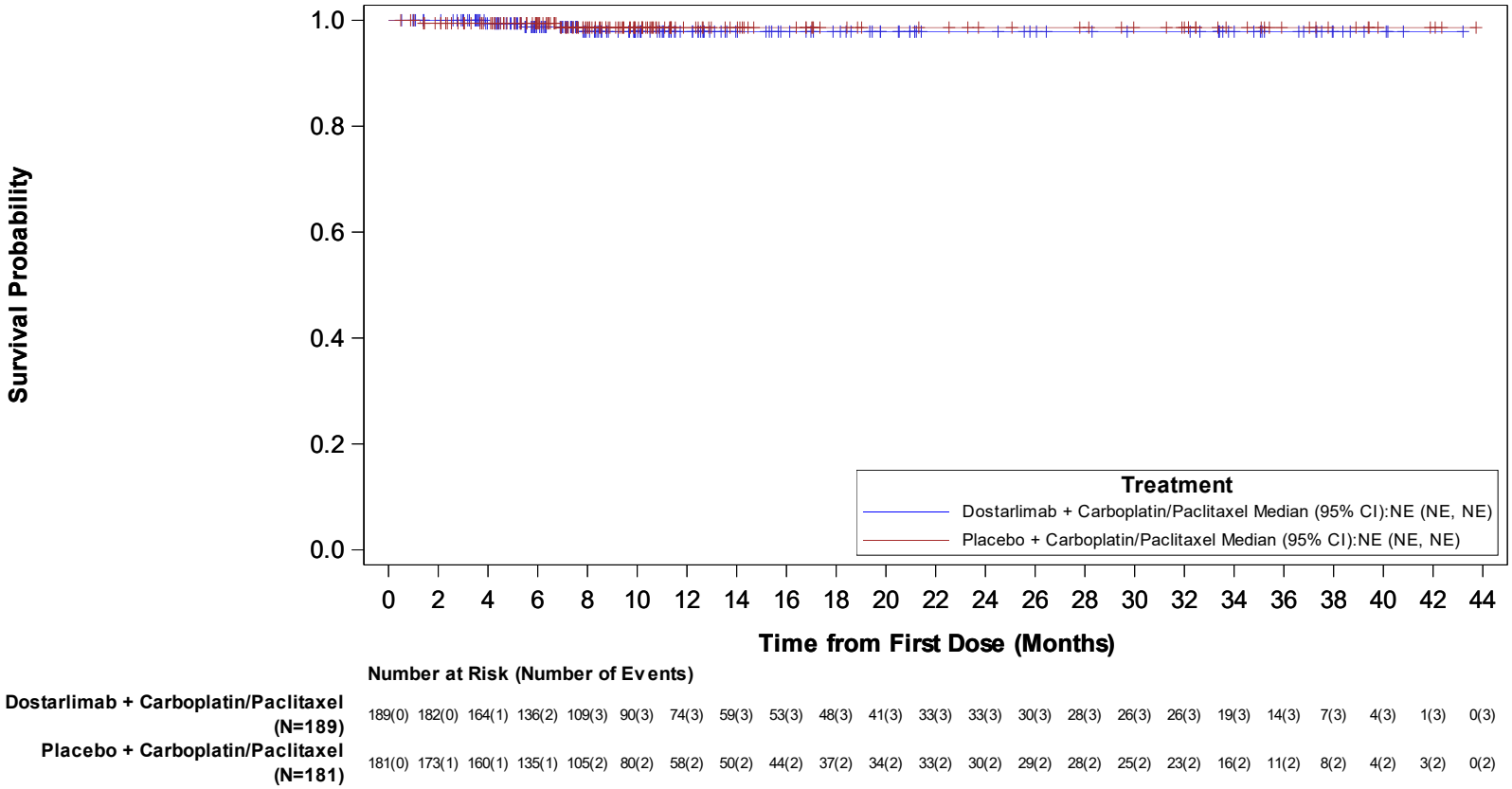
irAE Category: Immune-mediated Hepatic



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_5302_km_irae_ge3.sas, Output: f_3_5302_km_irae_ge3.rtf, Generated on: 20SEP2024 14:20,
Data Cutoff Date: 22SEP2023

Figure 3.5302 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category (Safety Analysis Set): MMRp/MSS Subjects

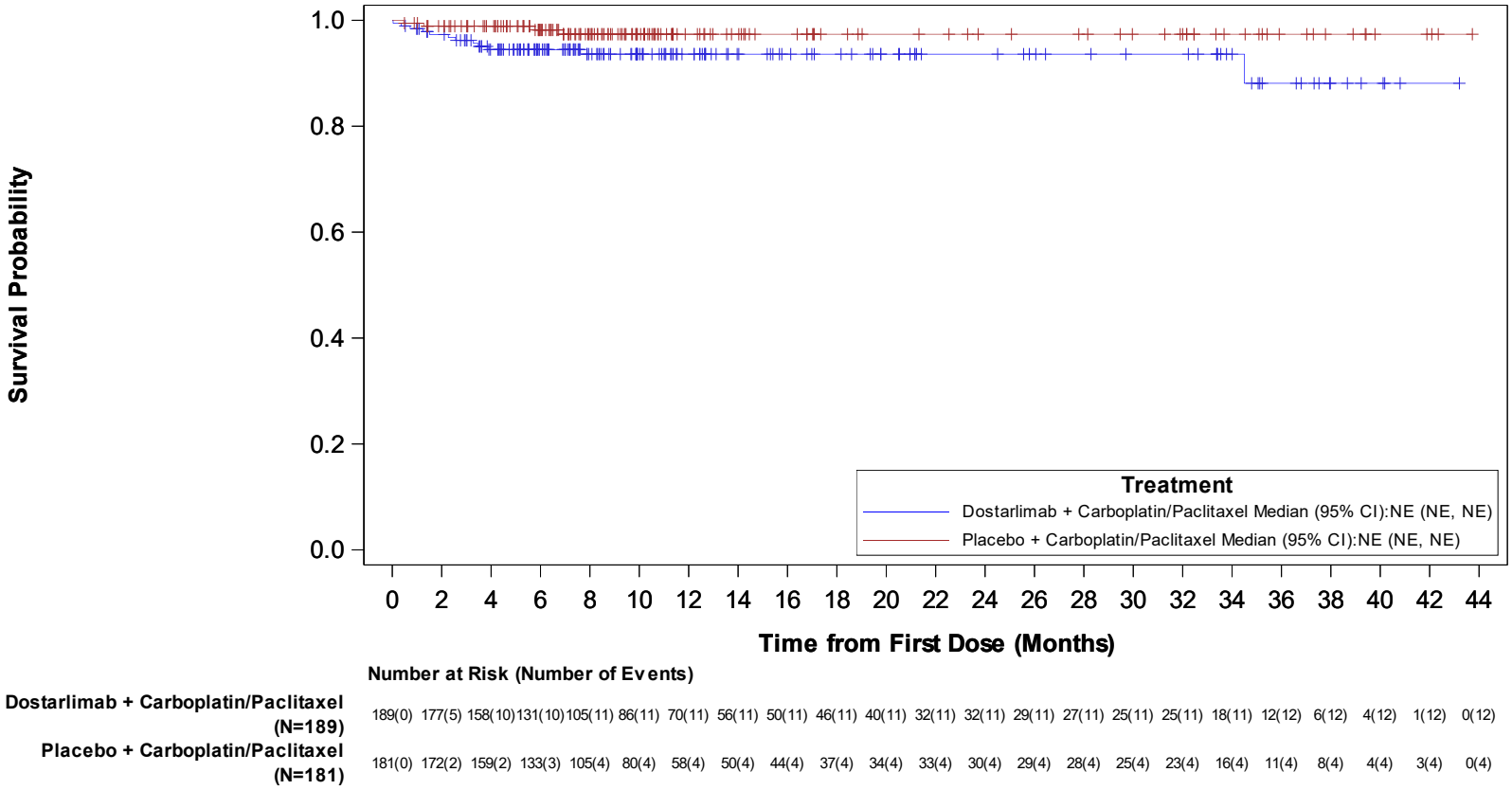
irAE Category: Immune-mediated Endocrinopathies



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_5302_km_irae_ge3.sas, Output: f_3_5302_km_irae_ge3.rtf, Generated on: 20SEP2024 14:20,
Data Cutoff Date: 22SEP2023

Figure 3.5702 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category (Safety Analysis Set): MMRp/MS Subjects

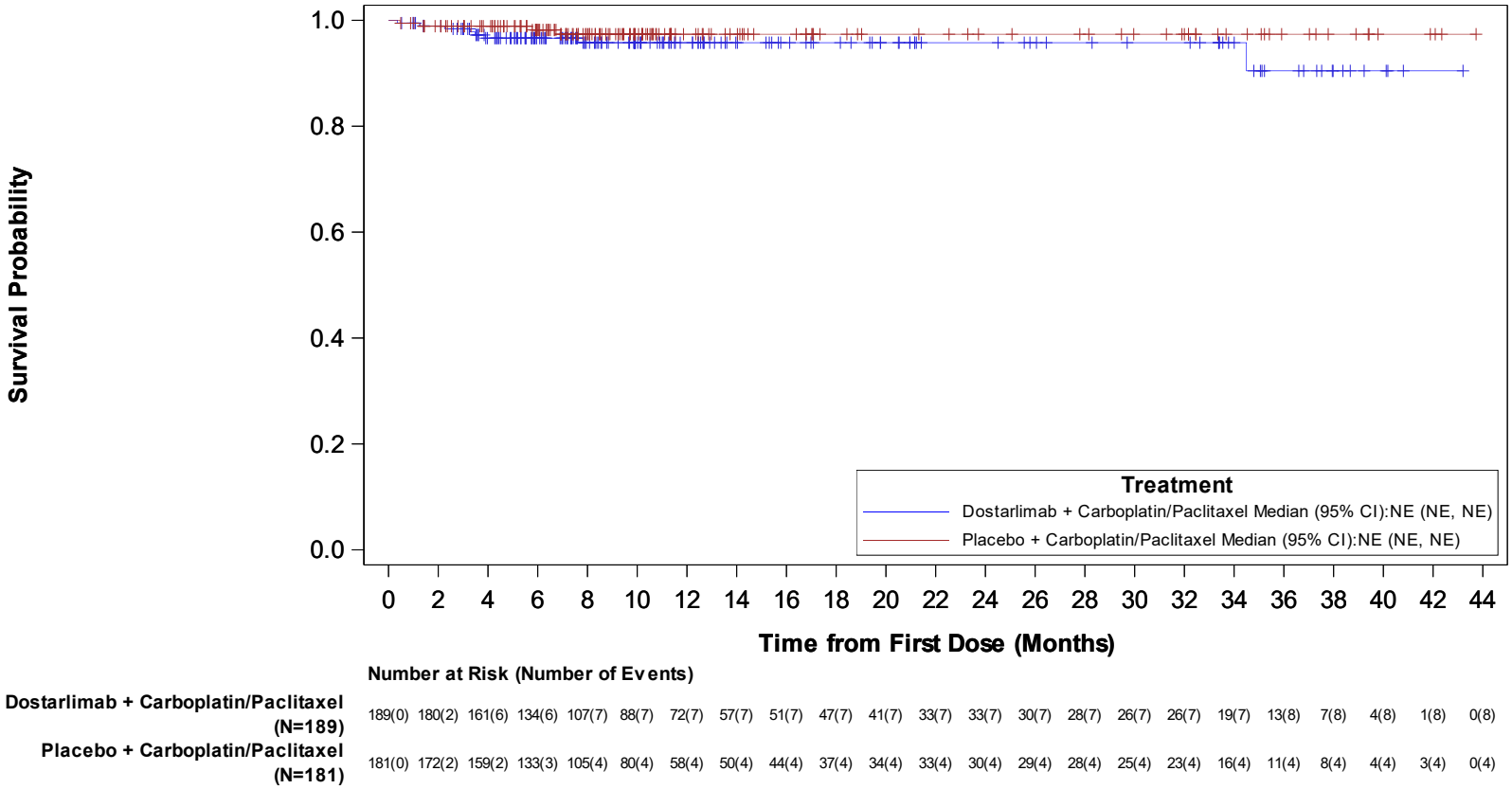
irAE Category: All irAEs



Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_5702_km_irae_ser.sas, Output: f_3_5702_km_irae_ser.rtf, Generated on: 20SEP2024 14:20,
Data Cutoff Date: 22SEP2023

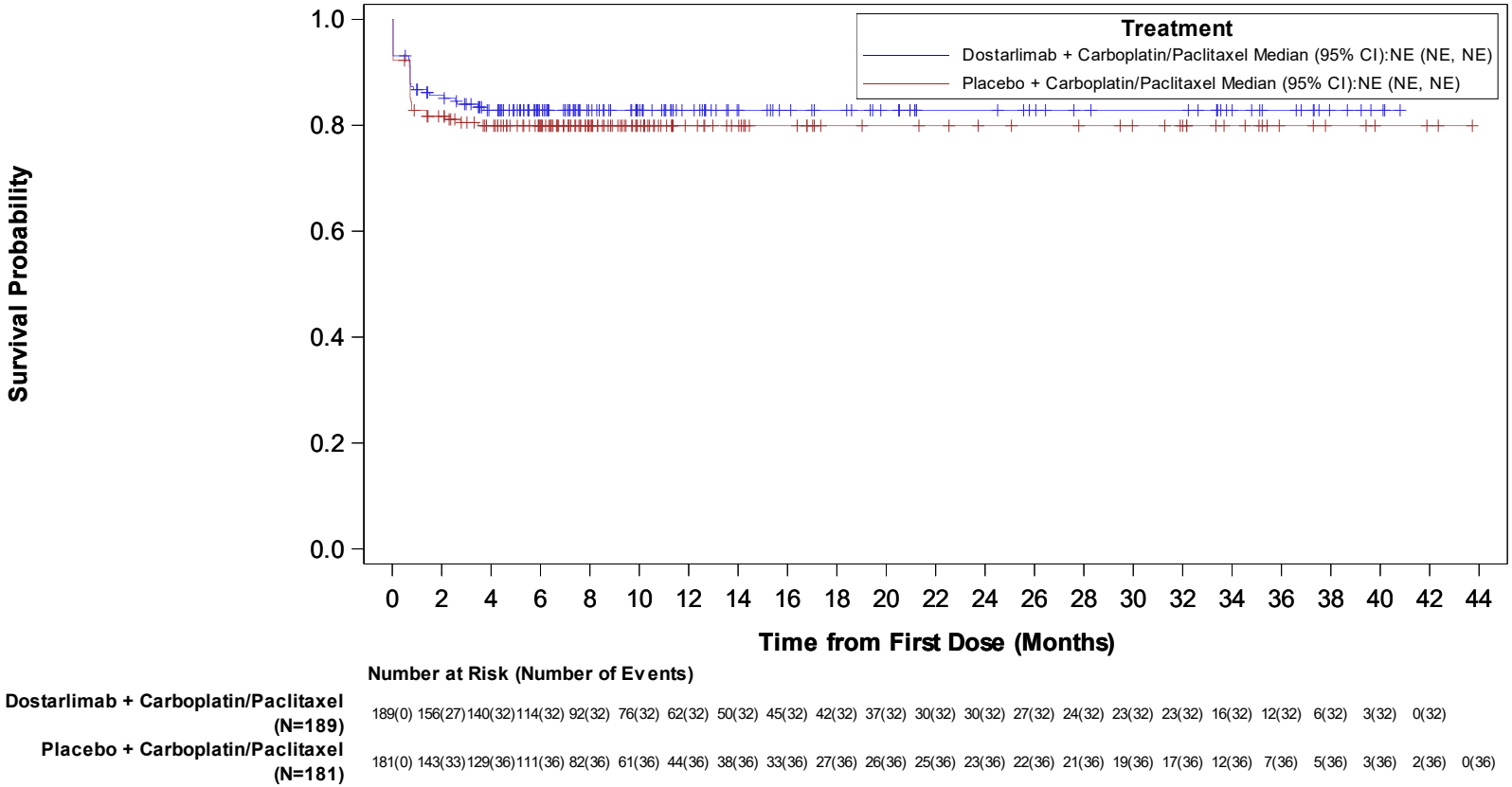
Figure 3.5702 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category (Safety Analysis Set): MMRp/MS Subjects

irAE Category: Non-hypersensitivity



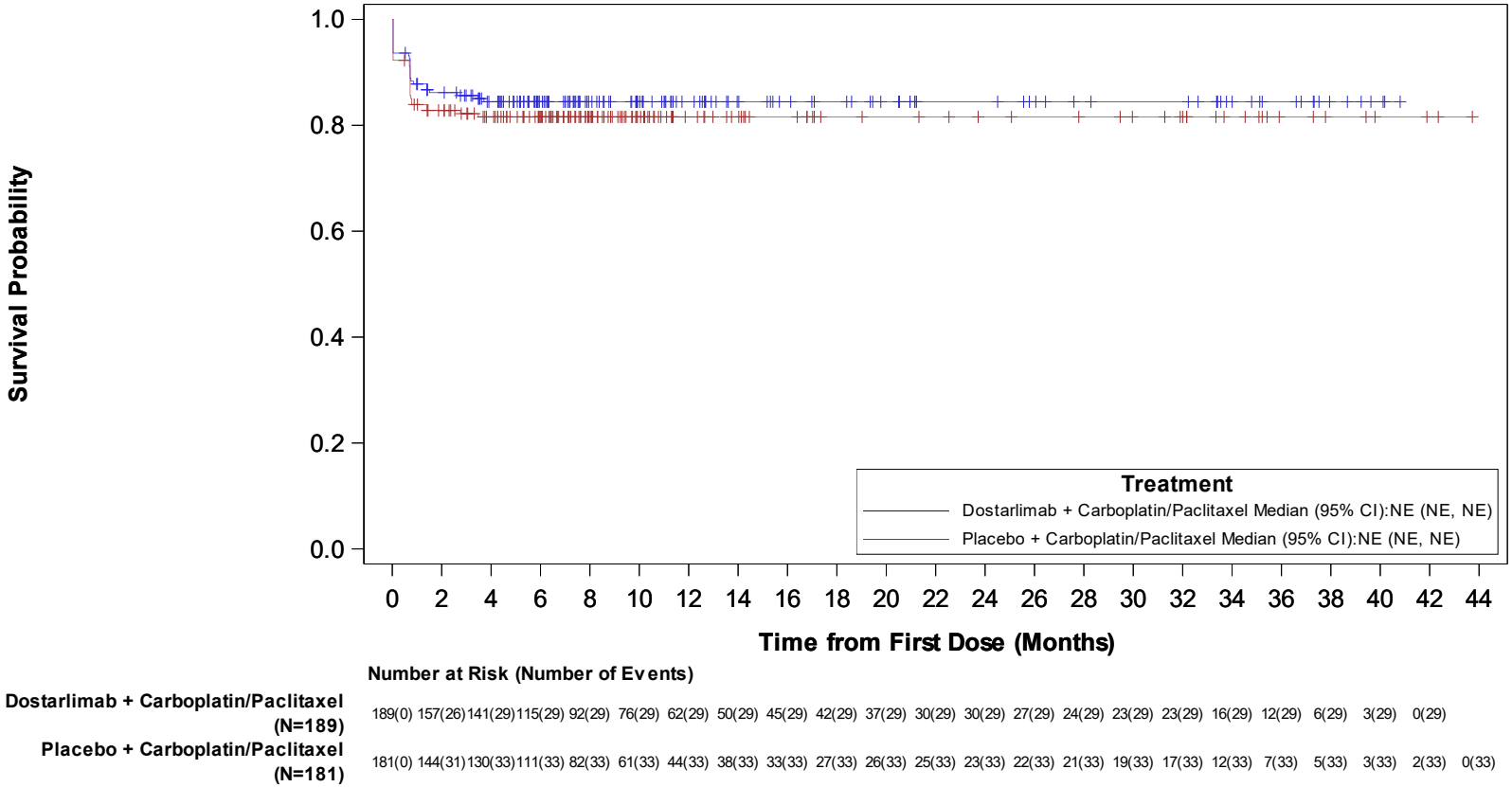
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
NE = Not Estimable.
Program: f_3_5702_km_irae_ser.sas, Output: f_3_5702_km_irae_ser.rtf, Generated on: 20SEP2024 14:20,
Data Cutoff Date: 22SEP2023

Figure 3.6102 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Infusion-Related Reactions
(Safety Analysis Set): MMRp/MSS Subjects



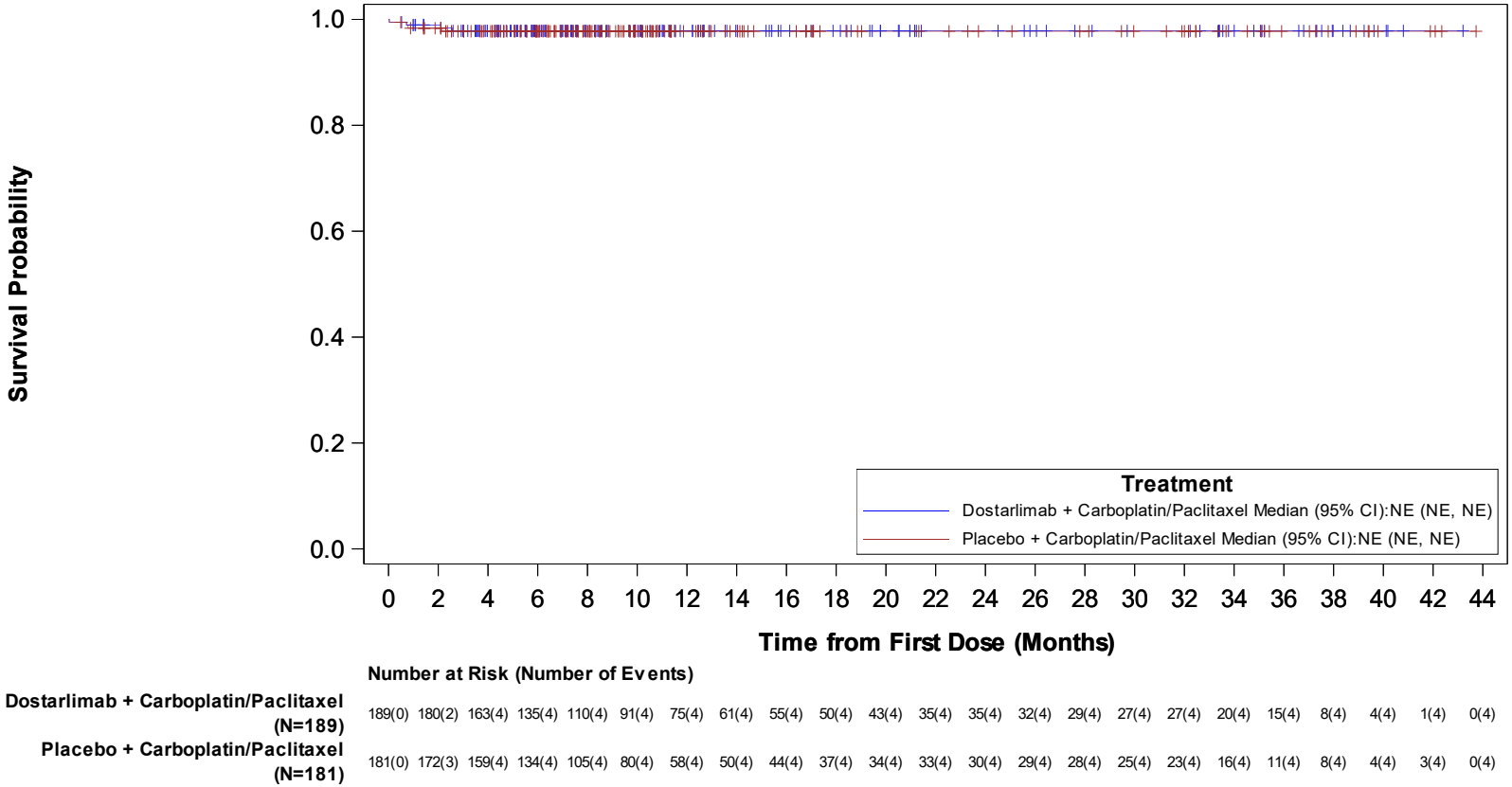
NE = Not Estimable.
Program: f_3_6102_km_irr.sas, Output: f_3_6102_km_irr.rtf, Generated on: 20SEP2024 17:25,
Data Cutoff Date: 22SEP2023

Figure 3.6502 Kaplan Meier Plot of Time to Treatment-Emergent Infusion-related reactions of Grade <=2
(Safety Analysis Set): MMRp/MSS Subject



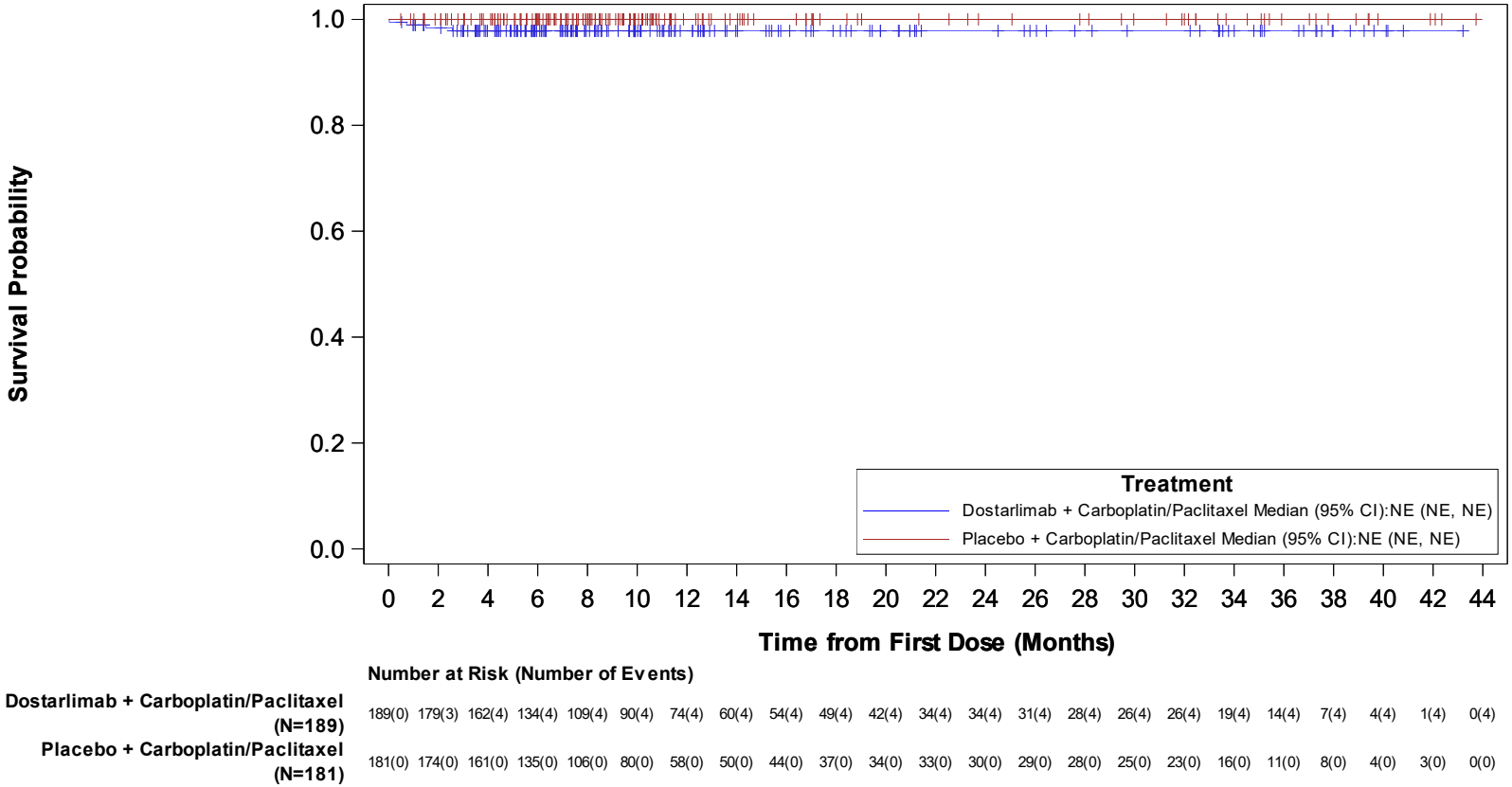
NE = Not Estimable.
Program: f_3_6502_km_ttirr_le2.sas, Output: f_3_6502_km_ttirr_le2.rtf, Generated on: 20SEP2024 12:09,
Data Cutoff Date: 22SEP2023

Figure 3.6902 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Infusion-Related Reactions of Grade >=3 (Safety Analysis Set): MMRp/MSS Subjects



NE = Not Estimable.
Program: f_3_6902_km_irr_ge3.sas, Output: f_3_6902_km_irr_ge3.rtf, Generated on: 19SEP2024 15:41,
Data Cutoff Date: 22SEP2023

Figure 3.7302 Kaplan Meier Plot of Time to Treatment-Emergent Serious Infusion-related reactions
(Safety Analysis Set):MMRp/MSS Subjects



NE = Not Estimable.
Program: f_3_7302_km_irr_ser.sas, Output: f_3_7302_km_irr_ser.rtf, Generated on: 20SEP2024 14:05,
Data Cutoff Date: 22SEP2023

Table 2.0201 Kaplan Meier Analysis of Overall Survival by Age Group (ITT Analysis Set): All Subjects

Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
Number of Subjects in the Subgroup	127	114
OS		
Status [n (%)]		
Events observed	54 (42.5%)	57 (50.0%)
Censored	73 (57.5%)	57 (50.0%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	21.0 (11.0, 28.6)	13.4 (11.1, 17.1)
50%	44.6 (32.6, NE)	35.5 (21.2, NE)
75%	NE (44.6, NE)	NE (NE, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_2_0201_km_os_age.sas, Output: t_2_0201_km_os_age.rtf, Generated on: 23JUL2024 19:24, Data Cutoff Date: 22SEP2023

Table 2.0201 Kaplan Meier Analysis of Overall Survival by Age Group (ITT Analysis Set): All Subjects

Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
OS probability (95% CI) at		
Month 6	94.4% (88.7%, 97.3%)	90.3% (83.1%, 94.5%)
Month 9	86.4% (79.0%, 91.3%)	87.6% (80.0%, 92.5%)
Month 12	82.3% (74.4%, 88.0%)	81.4% (72.9%, 87.4%)
Month 18	78.2% (69.9%, 84.5%)	65.9% (56.3%, 73.9%)
Month 24	74.1% (65.4%, 80.9%)	55.7% (46.0%, 64.4%)
Month 30	62.5% (53.3%, 70.4%)	51.0% (41.3%, 59.9%)
Month 36	56.5% (47.0%, 64.9%)	47.4% (37.2%, 57.0%)
Hazard ratio[b] (95% CI)	0.74 (0.508, 1.091)	
Hazard ratio[b] (99% CI)	0.74 (0.451, 1.230)	
p-value of 2-sided stratified log-rank test	0.1294	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_2_0201_km_os_age.sas, Output: t_2_0201_km_os_age.rtf, Generated on: 23JUL2024 19:24, Data Cutoff Date: 22SEP2023

Table 2.0201 Kaplan Meier Analysis of Overall Survival by Age Group (ITT Analysis Set): All Subjects

Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
Number of Subjects in the Subgroup	118	135
OS		
Status [n (%)]		
Events observed	55 (46.6%)	87 (64.4%)
Censored	63 (53.4%)	48 (35.6%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	18.9 (12.7, 23.2)	14.7 (11.2, 16.3)
50%	37.6 (27.6, NE)	26.1 (21.5, 32.9)
75%	NE (NE, NE)	41.9 (36.6, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_2_0201_km_os_age.sas, Output: t_2_0201_km_os_age.rtf, Generated on: 23JUL2024 19:24, Data Cutoff Date: 22SEP2023

Table 2.0201 Kaplan Meier Analysis of Overall Survival by Age Group (ITT Analysis Set): All Subjects

Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
OS probability (95% CI) at		
Month 6	92.2% (85.6%, 95.9%)	94.8% (89.3%, 97.5%)
Month 9	88.7% (81.3%, 93.3%)	90.2% (83.8%, 94.2%)
Month 12	84.3% (76.2%, 89.8%)	80.5% (72.7%, 86.3%)
Month 18	76.3% (67.4%, 83.1%)	65.4% (56.6%, 72.8%)
Month 24	65.7% (56.2%, 73.6%)	53.0% (44.2%, 61.1%)
Month 30	58.4% (48.8%, 66.9%)	47.5% (38.7%, 55.7%)
Month 36	53.4% (43.7%, 62.2%)	39.2% (30.6%, 47.7%)
Hazard ratio[b] (95% CI)	0.70 (0.495, 0.982)	
Hazard ratio[b] (99% CI)	0.70 (0.445, 1.094)	
p-value of 2-sided stratified log-rank test	0.0388	
p-value from Interaction Test[c]	0.8551	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_2_0201_km_os_age.sas, Output: t_2_0201_km_os_age.rtf, Generated on: 23JUL2024 19:24, Data Cutoff Date: 22SEP2023

Table 2.0301 Kaplan Meier Analysis of Overall Survival by Region (ITT Analysis Set): All Subjects

Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
Number of Subjects in the Subgroup	171	187
OS		
Status [n (%)]		
Events observed	69 (40.4%)	112 (59.9%)
Censored	102 (59.6%)	75 (40.1%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	24.0 (19.2, 29.7)	13.3 (11.2, 15.9)
50%	44.6 (38.0, NE)	26.4 (21.5, 35.6)
75%	NE (NE, NE)	NE (41.9, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_2_0301_km_os_reg.sas, Output: t_2_0301_km_os_reg.rtf, Generated on: 23JUL2024 19:25, Data Cutoff Date: 22SEP2023

Table 2.0301 Kaplan Meier Analysis of Overall Survival by Region (ITT Analysis Set): All Subjects

Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
OS probability (95% CI) at		
Month 6	95.8% (91.4%, 98.0%)	92.0% (87.0%, 95.1%)
Month 9	91.6% (86.2%, 94.9%)	88.2% (82.6%, 92.1%)
Month 12	88.0% (82.0%, 92.1%)	80.1% (73.6%, 85.2%)
Month 18	83.2% (76.6%, 88.1%)	64.2% (56.9%, 70.7%)
Month 24	74.7% (67.4%, 80.7%)	53.2% (45.7%, 60.1%)
Month 30	66.2% (58.4%, 72.9%)	47.0% (39.6%, 54.0%)
Month 36	60.9% (52.9%, 67.9%)	41.9% (34.4%, 49.2%)
Hazard ratio[b] (95% CI)	0.56 (0.413, 0.757)	
Hazard ratio[b] (99% CI)	0.56 (0.376, 0.833)	
p-value of 2-sided stratified log-rank test	0.0001	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_2_0301_km_os_reg.sas, Output: t_2_0301_km_os_reg.rtf, Generated on: 23JUL2024 19:25, Data Cutoff Date: 22SEP2023

Table 2.0301 Kaplan Meier Analysis of Overall Survival by Region (ITT Analysis Set): All Subjects

Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
Number of Subjects in the Subgroup	74	62
OS		
Status [n (%)]		
Events observed	40 (54.1%)	32 (51.6%)
Censored	34 (45.9%)	30 (48.4%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	10.1 (6.2, 14.9)	15.7 (10.3, 20.0)
50%	28.6 (18.7, NE)	32.4 (20.0, NE)
75%	NE (NE, NE)	NE (36.5, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_2_0301_km_os_reg.sas, Output: t_2_0301_km_os_reg.rtf, Generated on: 23JUL2024 19:25, Data Cutoff Date: 22SEP2023

Table 2.0301 Kaplan Meier Analysis of Overall Survival by Region (ITT Analysis Set): All Subjects

Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
OS probability (95% CI) at		
Month 6	87.7% (77.6%, 93.4%)	95.0% (85.3%, 98.4%)
Month 9	78.0% (66.6%, 85.9%)	91.7% (81.1%, 96.4%)
Month 12	72.4% (60.6%, 81.2%)	83.3% (71.2%, 90.7%)
Month 18	63.7% (51.4%, 73.7%)	69.8% (56.5%, 79.8%)
Month 24	59.3% (46.9%, 69.7%)	57.6% (43.9%, 69.0%)
Month 30	47.1% (35.0%, 58.3%)	55.8% (42.2%, 67.4%)
Month 36	38.9% (26.1%, 51.5%)	46.0% (32.0%, 58.9%)
Hazard ratio[b] (95% CI)	1.09 (0.668, 1.768)	
Hazard ratio[b] (99% CI)	1.09 (0.573, 2.060)	
p-value of 2-sided stratified log-rank test	0.7133	
p-value from Interaction Test[c]	0.0143	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_2_0301_km_os_reg.sas, Output: t_2_0301_km_os_reg.rtf, Generated on: 23JUL2024 19:25, Data Cutoff Date: 22SEP2023

Table 2.0401 Kaplan Meier Analysis of Overall Survival by Disease Status (ITT Analysis Set): All Subjects

Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
Number of Subjects in the Subgroup	117	119
OS		
Status [n (%)]		
Events observed	48 (41.0%)	77 (64.7%)
Censored	69 (59.0%)	42 (35.3%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	24.3 (17.4, 29.7)	13.2 (11.2, 17.3)
50%	44.6 (34.1, NE)	23.1 (19.0, 31.4)
75%	NE (44.6, NE)	42.2 (39.7, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0401_km_os_dstat.sas, Output: t_2_0401_km_os_dstat.rtf, Generated on: 23JUL2024 19:26, Data Cutoff Date: 22SEP2023

Table 2.0401 Kaplan Meier Analysis of Overall Survival by Disease Status (ITT Analysis Set): All Subjects

Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
OS probability (95% CI) at		
Month 6	95.7% (89.9%, 98.2%)	92.4% (86.0%, 96.0%)
Month 9	90.4% (83.3%, 94.6%)	86.6% (79.0%, 91.5%)
Month 12	86.0% (78.2%, 91.2%)	81.5% (73.3%, 87.4%)
Month 18	82.4% (74.1%, 88.3%)	65.3% (56.0%, 73.1%)
Month 24	75.3% (66.2%, 82.2%)	47.8% (38.5%, 56.6%)
Month 30	64.5% (54.8%, 72.5%)	43.4% (34.3%, 52.2%)
Month 36	59.1% (49.2%, 67.7%)	38.5% (29.6%, 47.4%)
Hazard ratio[b] (95% CI)	0.53 (0.366, 0.756)	
Hazard ratio[b] (99% CI)	0.53 (0.326, 0.847)	
p-value of 2-sided stratified log-rank test	0.0004	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0401_km_os_dstat.sas, Output: t_2_0401_km_os_dstat.rtf, Generated on: 23JUL2024 19:26, Data Cutoff Date: 22SEP2023

Table 2.0401 Kaplan Meier Analysis of Overall Survival by Disease Status (ITT Analysis Set): All Subjects

Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
Number of Subjects in the Subgroup	44	47
OS		
Status [n (%)]		
Events observed	18 (40.9%)	14 (29.8%)
Censored	26 (59.1%)	33 (70.2%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	23.7 (13.0, 31.2)	34.7 (13.6, 39.1)
50%	NE (30.7, NE)	NE (36.1, NE)
75%	NE (NE, NE)	NE (NE, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0401_km_os_dstat.sas, Output: t_2_0401_km_os_dstat.rtf, Generated on: 23JUL2024 19:26, Data Cutoff Date: 22SEP2023

Table 2.0401 Kaplan Meier Analysis of Overall Survival by Disease Status (ITT Analysis Set): All Subjects

Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
OS probability (95% CI) at		
Month 6	95.5% (83.0%, 98.8%)	95.5% (83.2%, 98.9%)
Month 9	90.9% (77.6%, 96.5%)	95.5% (83.2%, 98.9%)
Month 12	90.9% (77.6%, 96.5%)	93.2% (80.5%, 97.8%)
Month 18	81.8% (66.9%, 90.5%)	86.2% (71.8%, 93.5%)
Month 24	75.0% (59.4%, 85.3%)	81.4% (66.2%, 90.2%)
Month 30	68.0% (52.0%, 79.6%)	79.0% (63.5%, 88.5%)
Month 36	60.6% (44.4%, 73.4%)	72.3% (55.0%, 83.9%)
Hazard ratio[b] (95% CI)	1.34 (0.664, 2.694)	
Hazard ratio[b] (99% CI)	1.34 (0.533, 3.356)	
p-value of 2-sided stratified log-rank test	0.4138	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0401_km_os_dstat.sas, Output: t_2_0401_km_os_dstat.rtf, Generated on: 23JUL2024 19:26, Data Cutoff Date: 22SEP2023

Table 2.0401 Kaplan Meier Analysis of Overall Survival by Disease Status (ITT Analysis Set): All Subjects

Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
Number of Subjects in the Subgroup	84	83
OS		
Status [n (%)]		
Events observed	43 (51.2%)	53 (63.9%)
Censored	41 (48.8%)	30 (36.1%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	12.7 (7.5, 18.9)	11.6 (9.6, 15.0)
50%	31.3 (21.0, NE)	22.1 (15.8, 33.6)
75%	NE (NE, NE)	NE (35.5, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0401_km_os_dstat.sas, Output: t_2_0401_km_os_dstat.rtf, Generated on: 23JUL2024 19:26, Data Cutoff Date: 22SEP2023

Table 2.0401 Kaplan Meier Analysis of Overall Survival by Disease Status (ITT Analysis Set): All Subjects

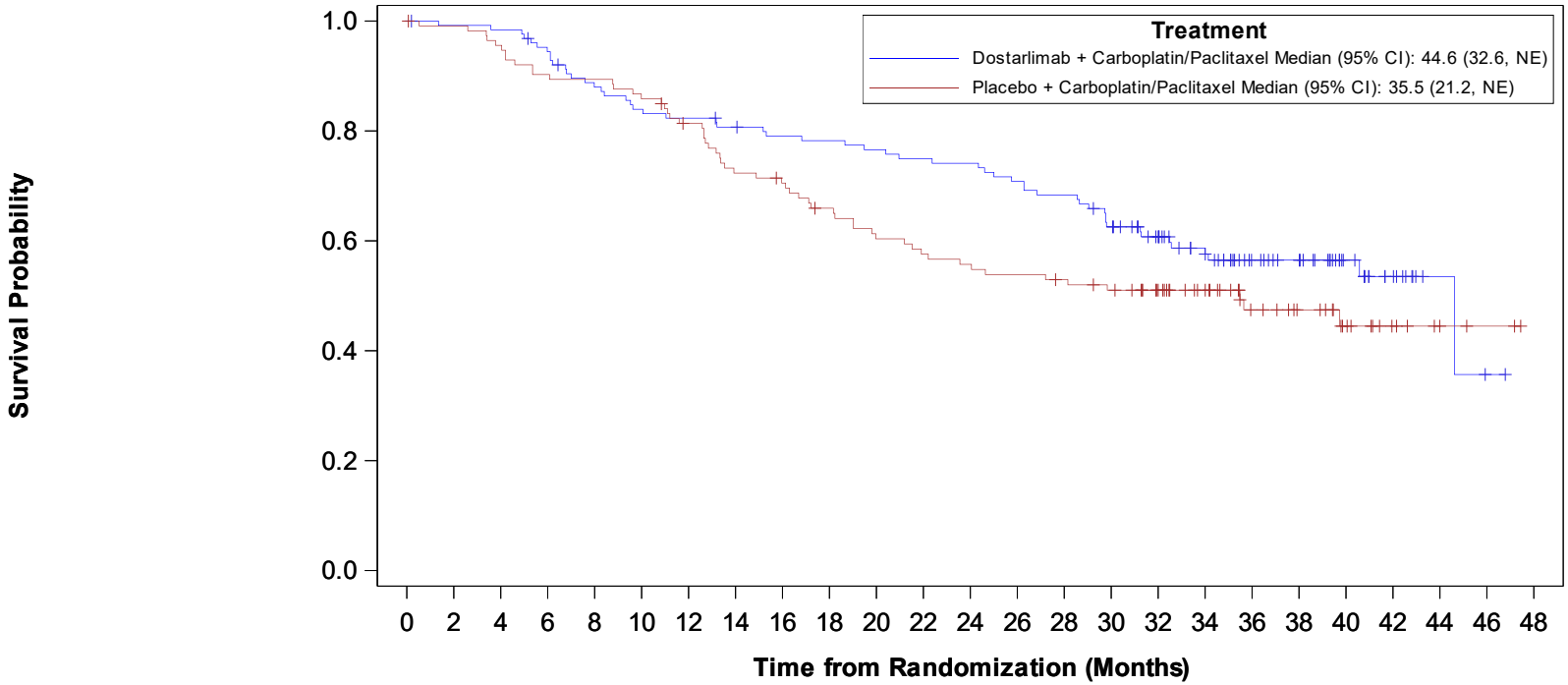
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=245)	Placebo + Carboplatin/Paclitaxel (N=249)
OS probability (95% CI) at		
Month 6	88.9% (79.8%, 94.1%)	91.6% (83.1%, 95.9%)
Month 9	81.4% (71.0%, 88.3%)	89.2% (80.2%, 94.2%)
Month 12	75.1% (64.2%, 83.2%)	73.5% (62.6%, 81.7%)
Month 18	67.5% (56.1%, 76.6%)	55.3% (44.0%, 65.3%)
Month 24	59.9% (48.3%, 69.7%)	49.2% (38.0%, 59.4%)
Month 30	50.9% (39.4%, 61.2%)	41.6% (30.8%, 52.0%)
Month 36	45.8% (34.2%, 56.6%)	31.8% (20.3%, 44.0%)
Hazard ratio[b] (95% CI)	0.80 (0.533, 1.198)	
Hazard ratio[b] (99% CI)	0.80 (0.470, 1.361)	
p-value of 2-sided stratified log-rank test	0.2762	
p-value from Interaction Test[c]	0.0716	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0401_km_os_dstat.sas, Output: t_2_0401_km_os_dstat.rtf, Generated on: 23JUL2024 19:26, Data Cutoff Date: 22SEP2023

Figure 2.0101 Graph of Kaplan Meier Curves of Overall Survival by Age Group
(ITT Analysis Set): All Subjects

Age Group: <65



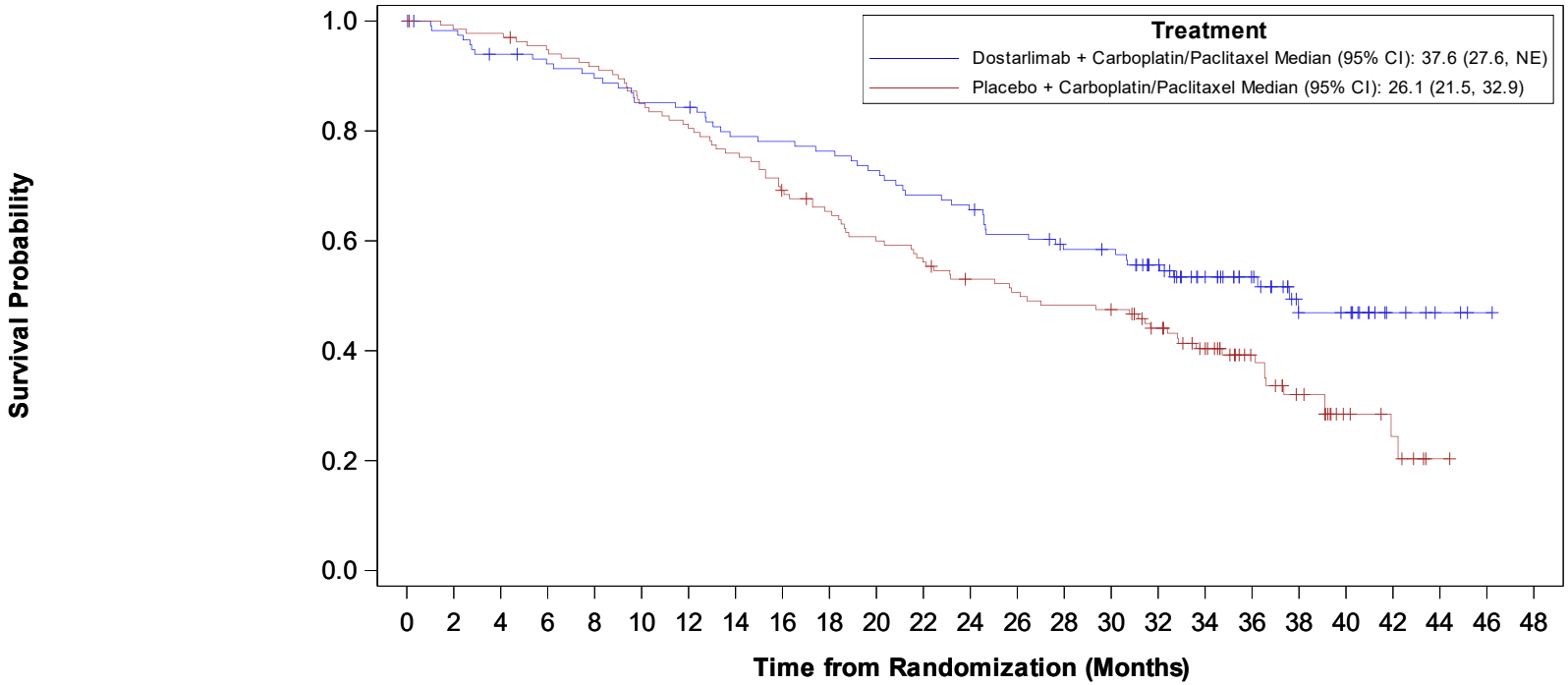
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=245)	127(0) 125(1) 124(2) 118(7) 109(15) 104(20) 102(22) 99(24) 96(26) 95(27) 93(29) 91(31) 90(32) 86(36) 83(39) 75(46) 65(48) 54(50) 39(52) 34(52) 20(52) 11(53) 3(53) 1(54) 0(54)
Placebo + Carboplatin/Paclitaxel (N=249)	114(0) 112(1) 108(5) 102(11) 101(12) 97(16) 90(21) 80(31) 77(33) 71(38) 65(44) 62(47) 60(49) 58(51) 56(52) 53(54) 46(54) 37(54) 25(56) 20(56) 13(57) 7(57) 3(57) 2(57) 0(57)

NE = Not Estimable.
Program: f_2_0101_km_os_age.sas, Output: f_2_0101_km_os_age.rtf, Generated on: 23JUL2024 19:29,
Data Cutoff Date: 22SEP2023

Figure 2.0101 Graph of Kaplan Meier Curves of Overall Survival by Age Group
(ITT Analysis Set): All Subjects

Age Group: >=65



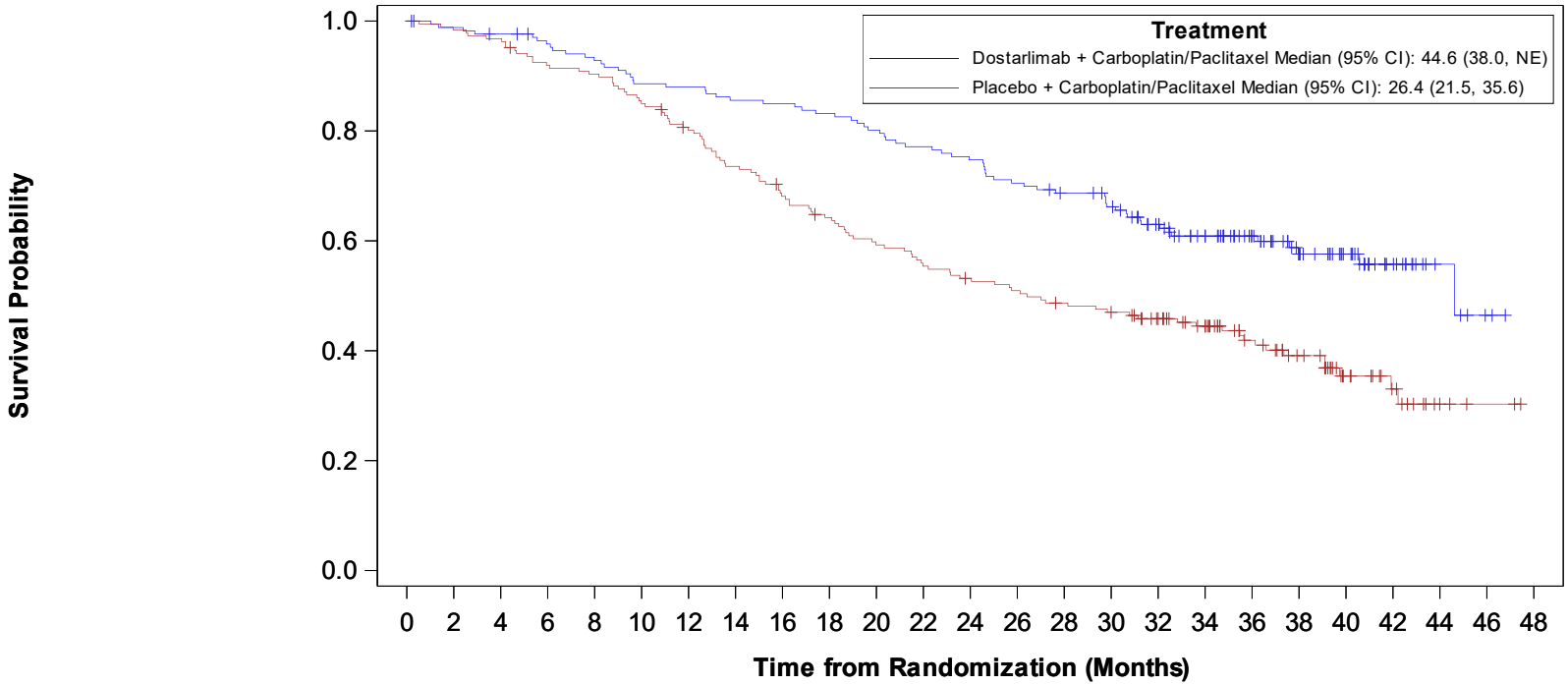
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=245)	118(0) 114(2) 108(7) 105(9) 102(12) 97(17) 96(18) 89(24) 88(25) 86(27) 82(31) 77(36) 74(39) 68(44) 63(47) 62(47) 53(50) 41(52) 31(52) 18(55) 17(55) 6(55) 3(55) 1(55) 0(55)
Placebo + Carboplatin/Paclitaxel (N=249)	135(0) 132(2) 131(3) 126(7) 122(11) 113(20) 107(26) 101(32) 91(41) 85(46) 78(53) 73(58) 67(62) 64(65) 61(68) 59(69) 50(73) 41(77) 28(78) 19(83) 9(85) 6(86) 1(87) 0(87)

NE = Not Estimable.
Program: f_2_0101_km_os_age.sas, Output: f_2_0101_km_os_age.rtf, Generated on: 23JUL2024 19:29,
Data Cutoff Date: 22SEP2023

Figure 2.0201 Graph of Kaplan Meier Curves of Overall Survival by Region
(ITT Analysis Set): All Subjects

Region: North America



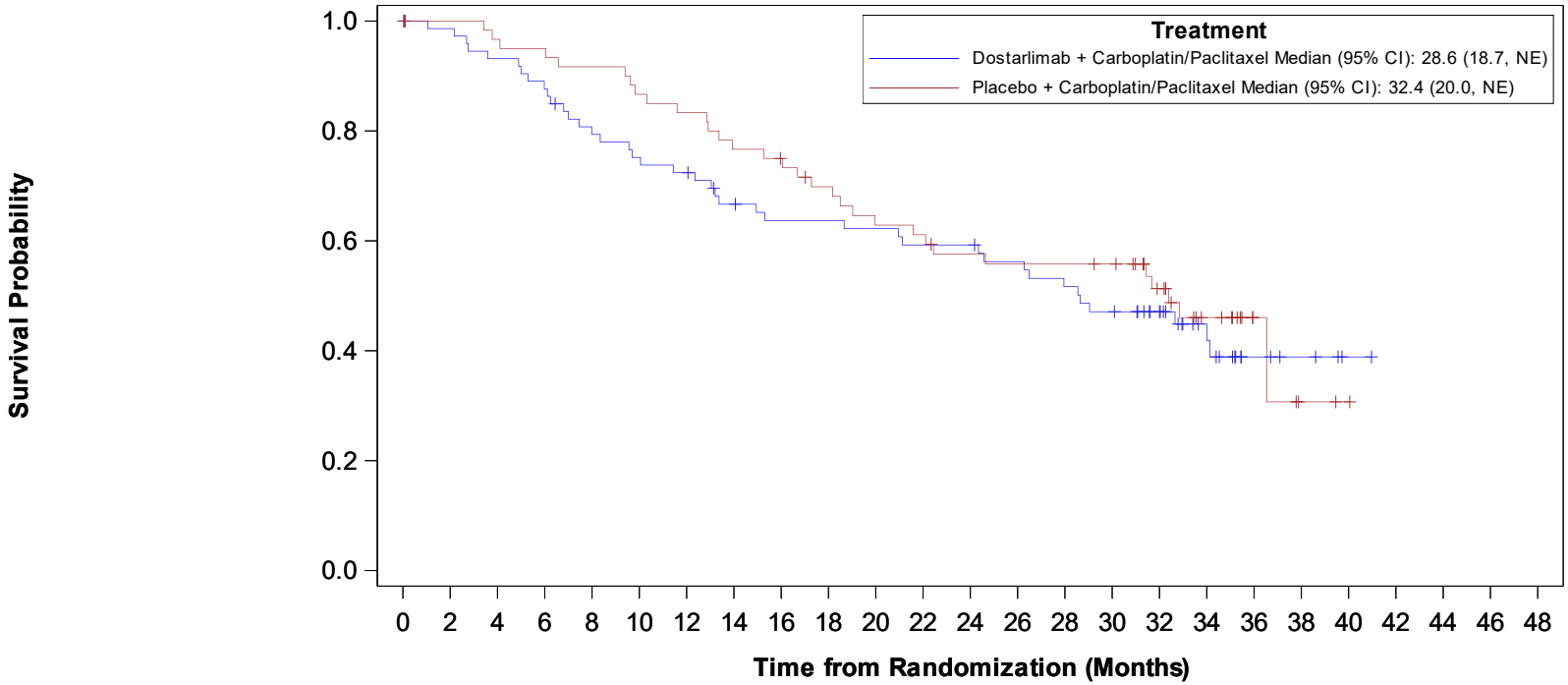
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=245)	171(0) 167(2) 164(4) 159(7) 154(12) 147(19) 146(20) 142(24) 141(25) 138(28) 133(33) 128(38) 124(42) 117(49) 112(52) 106(56) 93(61) 80(64) 64(64) 48(67) 36(67) 17(68) 6(68) 2(69) 0(69)
Placebo + Carboplatin/Paclitaxel (N=249)	187(0) 184(3) 181(6) 171(15) 168(18) 158(28) 147(37) 135(49) 124(59) 116(66) 107(75) 100(82) 95(86) 91(90) 86(94) 82(97) 74(99) 64(101) 47(104) 37(107) 21(110) 13(111) 4(112) 2(112) 0(112)

NE = Not Estimable.
Program: f_2_0201_km_os_reg.sas, Output: f_2_0201_km_os_reg.rtf, Generated on: 23JUL2024 19:31,
Data Cutoff Date: 22SEP2023

Figure 2.0201 Graph of Kaplan Meier Curves of Overall Survival by Region (ITT Analysis Set): All Subjects

Region: Europe



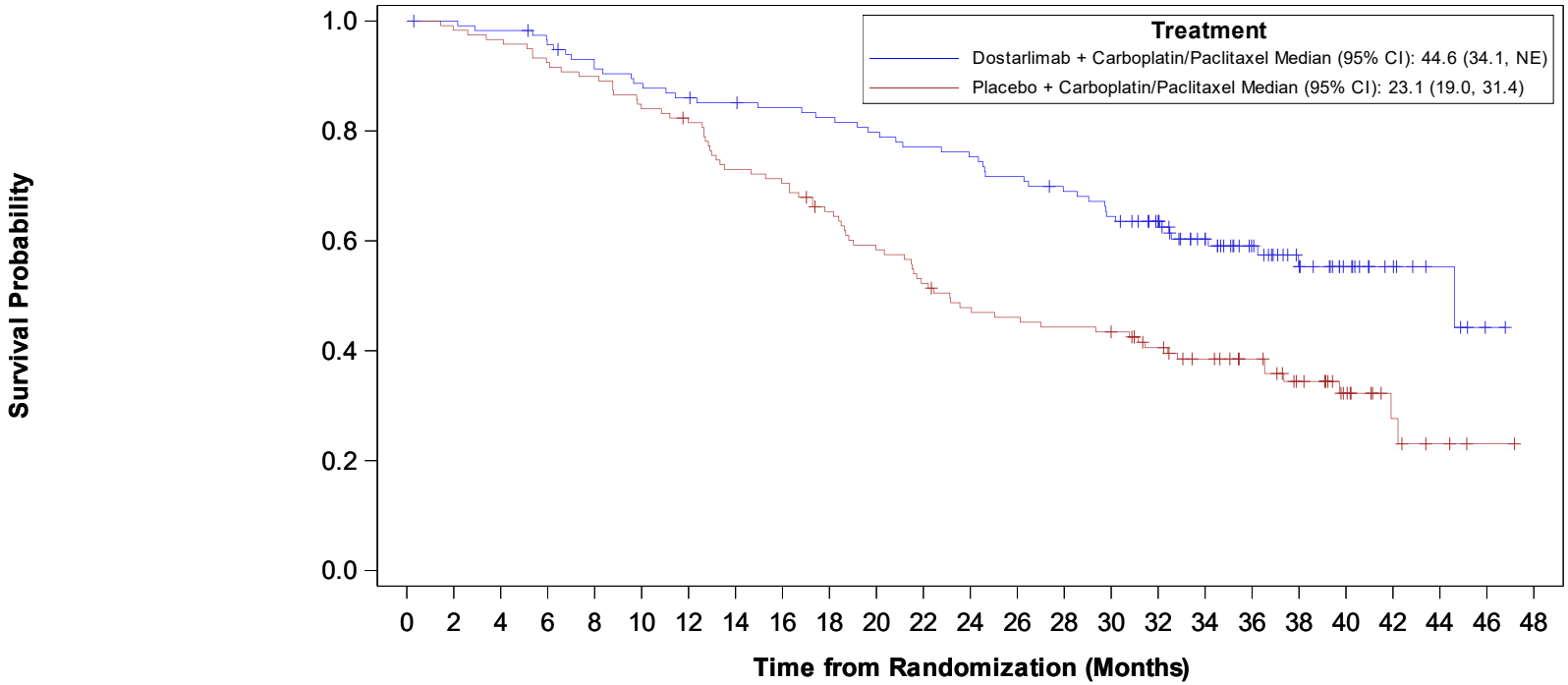
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=245)	74(0)	72(1)	68(5)	64(9)	57(15)	54(18)	52(20)	46(24)	43(26)	43(26)	42(27)	40(29)	40(29)	37(31)	34(34)	31(37)	25(37)	15(38)	6(40)	4(40)	1(40)	0(40)
Placebo + Carboplatin/Paclitaxel (N=249)	62(0)	60(0)	58(2)	57(3)	55(5)	52(8)	50(10)	46(14)	44(15)	40(18)	36(22)	35(23)	32(25)	31(26)	31(26)	30(26)	22(28)	14(30)	6(30)	2(32)	1(32)	0(32)

NE = Not Estimable.
Program: f_2_0201_km_os_reg.sas, Output: f_2_0201_km_os_reg.rtf, Generated on: 23JUL2024 19:31,
Data Cutoff Date: 22SEP2023

Figure 2.0301 Graph of Kaplan Meier Curves of Overall Survival by Disease Status (ITT Analysis Set): All Subjects

Disease Status: Recurrent



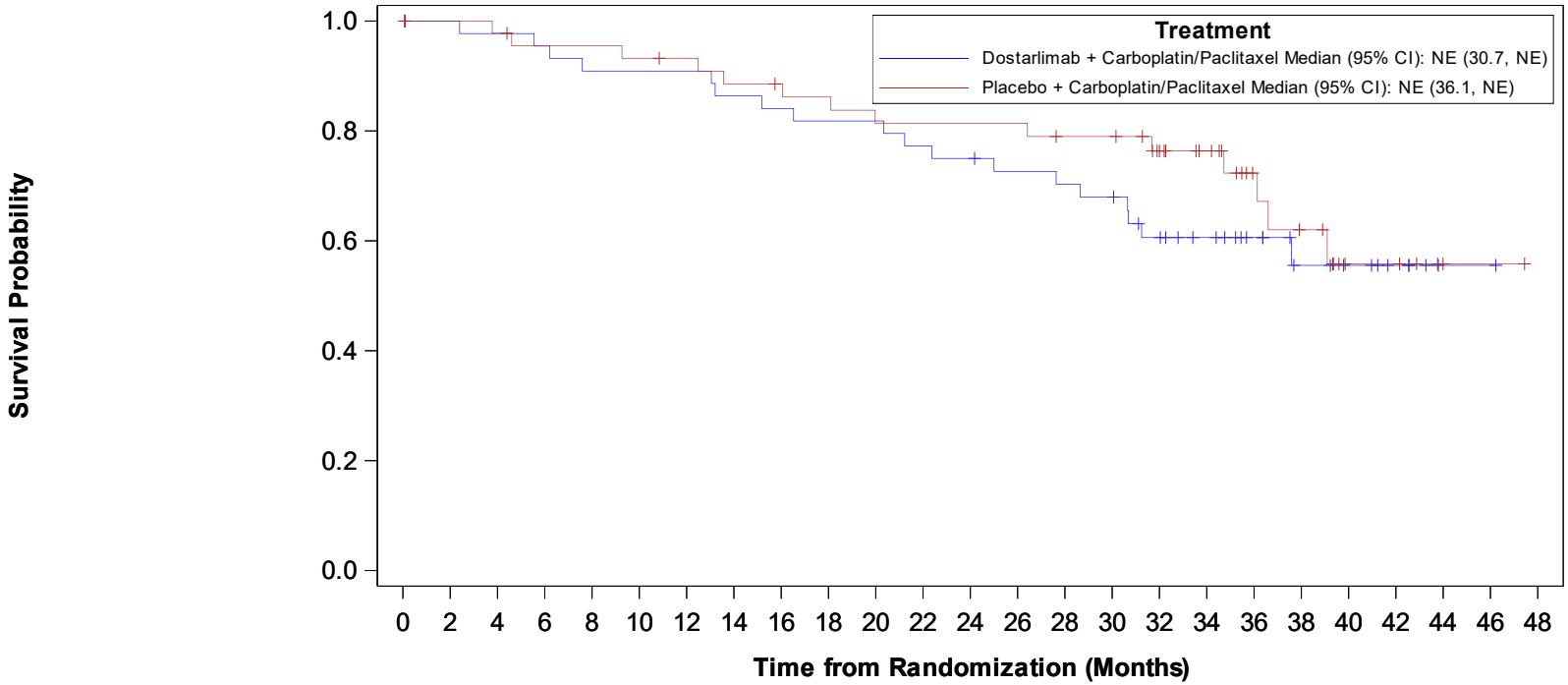
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=245)	117(0) 116(0) 114(2) 110(5) 104(10) 101(13) 98(16) 96(17) 94(18) 92(20) 89(23) 86(26) 84(28) 80(32) 76(35) 71(40) 64(41) 50(44) 37(45) 26(47) 17(47) 9(47) 5(47) 1(48) 0(48)
Placebo + Carboplatin/Paclitaxel (N=249)	119(0) 117(2) 115(4) 110(9) 107(12) 100(19) 96(22) 86(32) 83(35) 75(41) 67(49) 60(56) 54(61) 52(63) 50(65) 48(66) 41(69) 35(71) 30(71) 22(74) 13(75) 6(76) 3(77) 1(77) 0(77)

NE = Not Estimable.
Program: f_2_0301_km_os_dstat.sas, Output: f_2_0301_km_os_dstat.rtf, Generated on: 23JUL2024 19:32,
Data Cutoff Date: 22SEP2023

Figure 2.0301 Graph of Kaplan Meier Curves of Overall Survival by Disease Status
(ITT Analysis Set): All Subjects

Disease Status: Primary Stage III



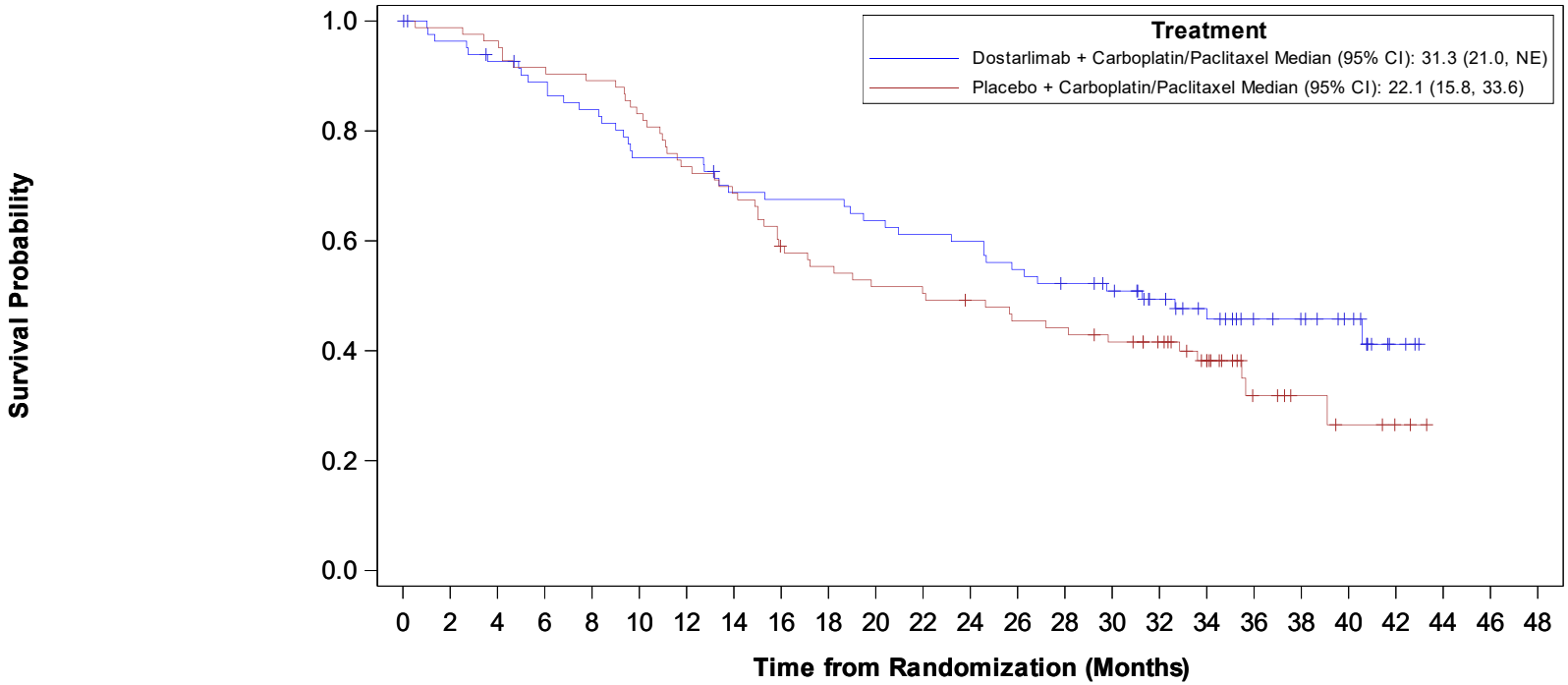
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=245)	44(0)	44(0)	43(1)	42(2)	40(4)	40(4)	40(4)	38(6)	37(7)	36(8)	36(8)	34(10)	33(11)	31(12)	30(13)	29(14)	24(17)	20(17)	15(17)	10(18)	8(18)	5(18)	1(18)	1(18)	0(18)
Placebo + Carboplatin/Paclitaxel (N=249)	47(0)	45(0)	44(1)	42(2)	42(2)	41(3)	40(3)	38(5)	37(5)	36(6)	34(8)	34(8)	34(8)	34(8)	32(9)	32(9)	27(10)	22(10)	14(11)	11(13)	5(14)	5(14)	1(14)	1(14)	0(14)

NE = Not Estimable.
Program: f_2_0301_km_os_dstat.sas, Output: f_2_0301_km_os_dstat.rtf, Generated on: 23JUL2024 19:32,
Data Cutoff Date: 22SEP2023

Figure 2.0301 Graph of Kaplan Meier Curves of Overall Survival by Disease Status
(ITT Analysis Set): All Subjects

Disease Status: Primary Stage IV



Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=245)	84(0)	79(3)	75(6)	71(9)	67(13)	60(20)	60(20)	54(25)	53(26)	53(26)	50(29)	48(31)	47(32)	43(36)	40(38)	37(39)	30(40)	25(41)	18(42)	16(42)	12(42)	3(43)	0(43)
Placebo + Carboplatin/Paclitaxel (N=249)	83(0)	82(1)	80(3)	76(7)	74(9)	69(14)	61(22)	57(26)	48(34)	45(37)	42(40)	41(41)	39(42)	36(45)	35(46)	32(48)	28(48)	21(50)	9(52)	6(52)	4(53)	2(53)	0(53)	

NE = Not Estimable.
Program: f_2_0301_km_os_dstat.sas, Output: f_2_0301_km_os_dstat.rtf, Generated on: 23JUL2024 19:32,
Data Cutoff Date: 22SEP2023

Table 2.0202 Kaplan Meier Analysis of Overall Survival by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
OS		
Status [n (%)]		
Events observed	49 (50.5%)	42 (50.0%)
Censored	48 (49.5%)	42 (50.0%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	16.8 (9.5, 25.8)	13.5 (11.0, 19.0)
50%	34.1 (29.0, NE)	35.6 (21.2, NE)
75%	44.6 (44.6, NE)	NE (NE, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_2_0202_km_os_age.sas, Output: t_2_0202_km_os_age.rtf, Generated on: 23JUL2024 19:25, Data Cutoff Date: 22SEP2023

Table 2.0202 Kaplan Meier Analysis of Overall Survival by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
OS probability (95% CI) at		
Month 6	94.8% (87.9%, 97.8%)	90.4% (81.7%, 95.1%)
Month 9	85.3% (76.4%, 91.0%)	89.2% (80.2%, 94.2%)
Month 12	80.0% (70.5%, 86.8%)	84.3% (74.6%, 90.6%)
Month 18	74.7% (64.7%, 82.3%)	67.2% (56.0%, 76.2%)
Month 24	70.4% (60.1%, 78.6%)	57.3% (45.8%, 67.1%)
Month 30	55.4% (44.8%, 64.8%)	52.3% (40.9%, 62.4%)
Month 36	48.7% (37.9%, 58.6%)	47.9% (36.1%, 58.8%)
Hazard ratio[b] (95% CI)	0.92 (0.608, 1.395)	
Hazard ratio[b] (99% CI)	0.92 (0.534, 1.589)	
p-value of 2-sided stratified log-rank test	0.7002	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_2_0202_km_os_age.sas, Output: t_2_0202_km_os_age.rtf, Generated on: 23JUL2024 19:25, Data Cutoff Date: 22SEP2023

Table 2.0202 Kaplan Meier Analysis of Overall Survival by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
OS		
Status [n (%)]		
Events observed	48 (50.5%)	67 (67.0%)
Censored	47 (49.5%)	33 (33.0%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	17.4 (12.4, 21.1)	13.2 (10.2, 16.3)
50%	30.7 (24.6, NE)	23.1 (18.5, 32.9)
75%	NE (NE, NE)	41.9 (36.5, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_2_0202_km_os_age.sas, Output: t_2_0202_km_os_age.rtf, Generated on: 23JUL2024 19:25, Data Cutoff Date: 22SEP2023

Table 2.0202 Kaplan Meier Analysis of Overall Survival by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
OS probability (95% CI) at		
Month 6	93.5% (86.1%, 97.0%)	95.9% (89.5%, 98.5%)
Month 9	89.1% (80.7%, 94.0%)	91.9% (84.4%, 95.8%)
Month 12	84.7% (75.6%, 90.7%)	78.6% (69.1%, 85.5%)
Month 18	74.7% (64.4%, 82.4%)	63.2% (52.8%, 71.9%)
Month 24	62.4% (51.6%, 71.5%)	49.7% (39.4%, 59.1%)
Month 30	53.4% (42.6%, 63.1%)	43.4% (33.4%, 52.9%)
Month 36	48.6% (37.9%, 58.5%)	37.1% (27.3%, 46.8%)
Hazard ratio[b] (95% CI)	0.73 (0.504, 1.066)	
Hazard ratio[b] (99% CI)	0.73 (0.448, 1.199)	
p-value of 2-sided stratified log-rank test	0.1049	
p-value from Interaction Test[c]	0.4393	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_2_0202_km_os_age.sas, Output: t_2_0202_km_os_age.rtf, Generated on: 23JUL2024 19:25, Data Cutoff Date: 22SEP2023

Table 2.0302 Kaplan Meier Analysis of Overall Survival by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
OS		
Status [n (%)]		
Events observed	61 (45.2%)	84 (61.3%)
Censored	74 (54.8%)	53 (38.7%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	21.2 (17.4, 25.8)	13.2 (11.0, 16.1)
50%	44.6 (30.7, NE)	25.8 (19.0, 35.6)
75%	NE (44.6, NE)	NE (39.7, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_2_0302_km_os_reg.sas, Output: t_2_0302_km_os_reg.rtf, Generated on: 23JUL2024 19:26, Data Cutoff Date: 22SEP2023

Table 2.0302 Kaplan Meier Analysis of Overall Survival by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
OS probability (95% CI) at		
Month 6	97.7% (93.1%, 99.3%)	92.7% (86.8%, 96.0%)
Month 9	93.1% (87.2%, 96.4%)	89.7% (83.3%, 93.8%)
Month 12	88.5% (81.6%, 92.9%)	80.2% (72.4%, 85.9%)
Month 18	82.3% (74.6%, 87.9%)	63.1% (54.4%, 70.6%)
Month 24	72.3% (63.8%, 79.2%)	51.8% (43.1%, 59.9%)
Month 30	61.4% (52.4%, 69.2%)	45.1% (36.5%, 53.2%)
Month 36	55.4% (46.3%, 63.6%)	40.9% (32.3%, 49.3%)
Hazard ratio[b] (95% CI)	0.61 (0.438, 0.851)	
Hazard ratio[b] (99% CI)	0.61 (0.395, 0.944)	
p-value of 2-sided stratified log-rank test	0.0033	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_2_0302_km_os_reg.sas, Output: t_2_0302_km_os_reg.rtf, Generated on: 23JUL2024 19:26, Data Cutoff Date: 22SEP2023

Table 2.0302 Kaplan Meier Analysis of Overall Survival by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
OS		
Status [n (%)]		
Events observed	36 (63.2%)	25 (53.2%)
Censored	21 (36.8%)	22 (46.8%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	8.2 (6.0, 13.2)	16.7 (9.8, 20.0)
50%	24.6 (13.2, 34.0)	32.4 (19.0, 36.5)
75%	NE (34.0, NE)	NE (36.5, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_2_0302_km_os_reg.sas, Output: t_2_0302_km_os_reg.rtf, Generated on: 23JUL2024 19:26, Data Cutoff Date: 22SEP2023

Table 2.0302 Kaplan Meier Analysis of Overall Survival by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
OS probability (95% CI) at		
Month 6	85.7% (73.5%, 92.6%)	95.6% (83.4%, 98.9%)
Month 9	73.2% (59.6%, 82.9%)	93.3% (80.7%, 97.8%)
Month 12	67.9% (53.9%, 78.4%)	84.4% (70.1%, 92.3%)
Month 18	56.7% (42.7%, 68.6%)	71.0% (55.3%, 82.0%)
Month 24	53.0% (39.0%, 65.1%)	57.1% (41.3%, 70.2%)
Month 30	37.8% (25.1%, 50.5%)	54.8% (39.0%, 68.0%)
Month 36	30.3% (17.2%, 44.4%)	45.2% (29.2%, 59.8%)
Hazard ratio[b] (95% CI)	1.43 (0.846, 2.405)	
Hazard ratio[b] (99% CI)	1.43 (0.718, 2.834)	
p-value of 2-sided stratified log-rank test	0.1694	
p-value from Interaction Test[c]	0.0056	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_2_0302_km_os_reg.sas, Output: t_2_0302_km_os_reg.rtf, Generated on: 23JUL2024 19:26, Data Cutoff Date: 22SEP2023

Table 2.0402 Kaplan Meier Analysis of Overall Survival by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
OS		
Status [n (%)]		
Events observed	45 (50.0%)	56 (64.4%)
Censored	45 (50.0%)	31 (35.6%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	19.6 (11.0, 24.6)	13.5 (12.0, 17.8)
50%	34.1 (28.6, NE)	21.9 (18.6, 36.5)
75%	NE (44.6, NE)	41.9 (37.4, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0402_km_os_dstat.sas, Output: t_2_0402_km_os_dstat.rtf, Generated on: 23JUL2024 19:27, Data Cutoff Date: 22SEP2023

Table 2.0402 Kaplan Meier Analysis of Overall Survival by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
OS probability (95% CI) at		
Month 6	95.5% (88.4%, 98.3%)	94.3% (86.7%, 97.6%)
Month 9	88.7% (79.9%, 93.7%)	89.7% (81.1%, 94.5%)
Month 12	83.0% (73.4%, 89.4%)	83.9% (74.3%, 90.1%)
Month 18	78.3% (68.1%, 85.6%)	65.2% (54.2%, 74.2%)
Month 24	70.1% (59.3%, 78.6%)	46.2% (35.4%, 56.3%)
Month 30	56.0% (44.9%, 65.7%)	41.3% (30.8%, 51.5%)
Month 36	49.0% (37.8%, 59.3%)	40.0% (29.5%, 50.2%)
Hazard ratio[b] (95% CI)	0.68 (0.456, 1.004)	
Hazard ratio[b] (99% CI)	0.68 (0.403, 1.137)	
p-value of 2-sided stratified log-rank test	0.0513	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0402_km_os_dstat.sas, Output: t_2_0402_km_os_dstat.rtf, Generated on: 23JUL2024 19:27, Data Cutoff Date: 22SEP2023

Table 2.0402 Kaplan Meier Analysis of Overall Survival by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
OS		
Status [n (%)]		
Events observed	15 (42.9%)	11 (33.3%)
Censored	20 (57.1%)	22 (66.7%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	25.0 (15.2, 31.2)	34.7 (9.3, 39.1)
50%	NE (30.7, NE)	NE (36.1, NE)
75%	NE (NE, NE)	NE (NE, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0402_km_os_dstat.sas, Output: t_2_0402_km_os_dstat.rtf, Generated on: 23JUL2024 19:27, Data Cutoff Date: 22SEP2023

Table 2.0402 Kaplan Meier Analysis of Overall Survival by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
OS probability (95% CI) at		
Month 6	100% (100%, 100%)	93.4% (76.2%, 98.3%)
Month 9	97.1% (81.4%, 99.6%)	93.4% (76.2%, 98.3%)
Month 12	97.1% (81.4%, 99.6%)	90.1% (72.4%, 96.7%)
Month 18	85.7% (69.0%, 93.8%)	83.4% (64.7%, 92.7%)
Month 24	77.1% (59.5%, 87.9%)	80.1% (60.9%, 90.5%)
Month 30	68.6% (50.5%, 81.2%)	80.1% (60.9%, 90.5%)
Month 36	59.5% (41.3%, 73.7%)	71.5% (50.4%, 84.9%)
Hazard ratio[b] (95% CI)	1.14 (0.522, 2.480)	
Hazard ratio[b] (99% CI)	1.14 (0.408, 3.169)	
p-value of 2-sided stratified log-rank test	0.7461	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0402_km_os_dstat.sas, Output: t_2_0402_km_os_dstat.rtf, Generated on: 23JUL2024 19:27, Data Cutoff Date: 22SEP2023

Table 2.0402 Kaplan Meier Analysis of Overall Survival by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
OS		
Status [n (%)]		
Events observed	37 (55.2%)	42 (65.6%)
Censored	30 (44.8%)	22 (34.4%)
Estimates for OS (months)		
Quartile (95% CI)[a]		
25%	9.5 (6.1, 15.3)	11.5 (9.4, 15.8)
50%	25.8 (18.7, NE)	22.1 (15.8, 32.9)
75%	NE (40.6, NE)	NE (33.6, NE)

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0402_km_os_dstat.sas, Output: t_2_0402_km_os_dstat.rtf, Generated on: 23JUL2024 19:27, Data Cutoff Date: 22SEP2023

Table 2.0402 Kaplan Meier Analysis of Overall Survival by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

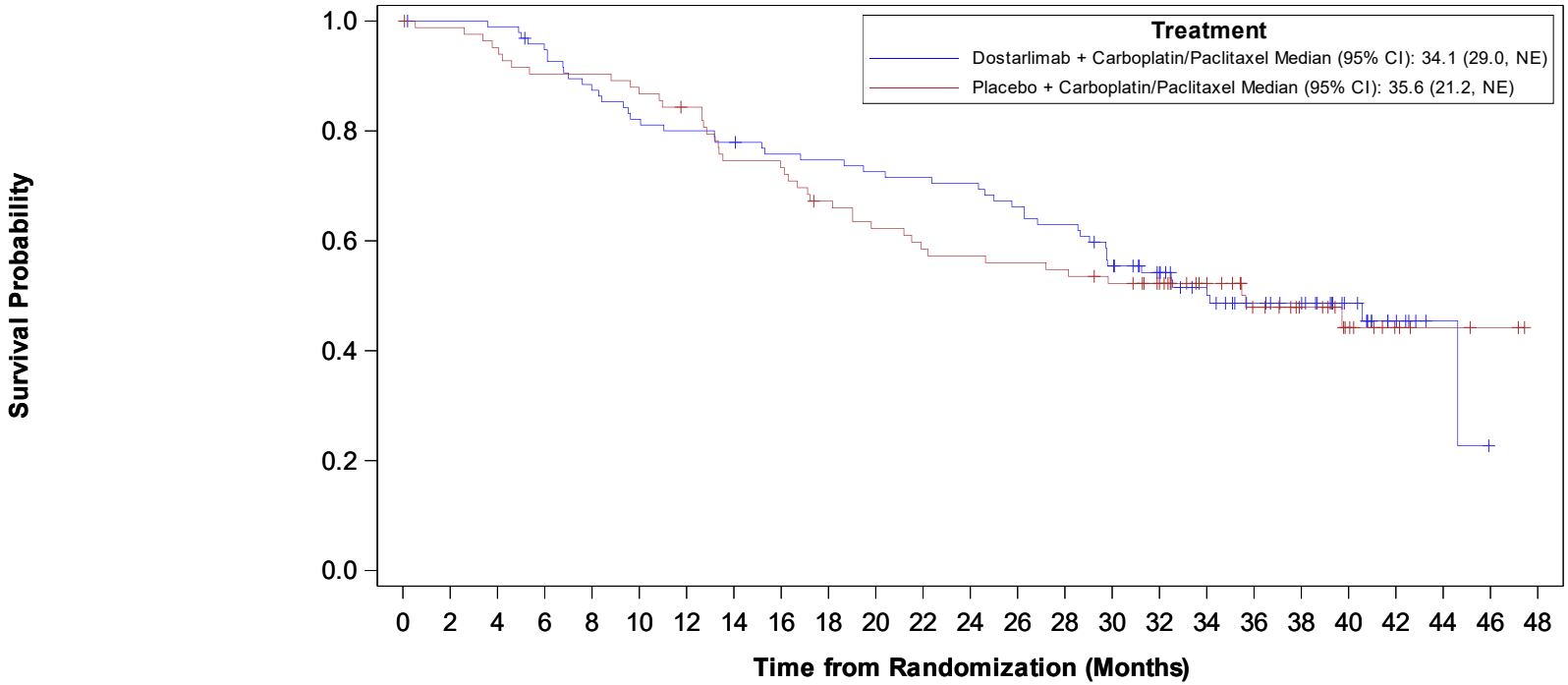
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
OS probability (95% CI) at		
Month 6	89.1% (78.4%, 94.6%)	92.2% (82.2%, 96.7%)
Month 9	79.5% (67.3%, 87.6%)	90.6% (80.3%, 95.7%)
Month 12	73.1% (60.4%, 82.4%)	73.4% (60.8%, 82.6%)
Month 18	63.6% (50.5%, 74.1%)	56.1% (43.1%, 67.3%)
Month 24	55.7% (42.6%, 66.9%)	49.7% (36.9%, 61.2%)
Month 30	44.3% (31.8%, 56.1%)	40.0% (28.0%, 51.8%)
Month 36	42.0% (29.5%, 54.0%)	26.9% (14.2%, 41.5%)
Hazard ratio[b] (95% CI)	0.87 (0.556, 1.351)	
Hazard ratio[b] (99% CI)	0.87 (0.483, 1.553)	
p-value of 2-sided stratified log-rank test	0.5242	
p-value from Interaction Test[c]	0.4920	

Note: OS: Overall Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0402_km_os_dstat.sas, Output: t_2_0402_km_os_dstat.rtf, Generated on: 23JUL2024 19:27, Data Cutoff Date: 22SEP2023

Figure 2.0102 Graph of Kaplan Meier Curves of Overall Survival by Age Group
(ITT Analysis Set): MMRp/MSS Subjects

Age Group: <65



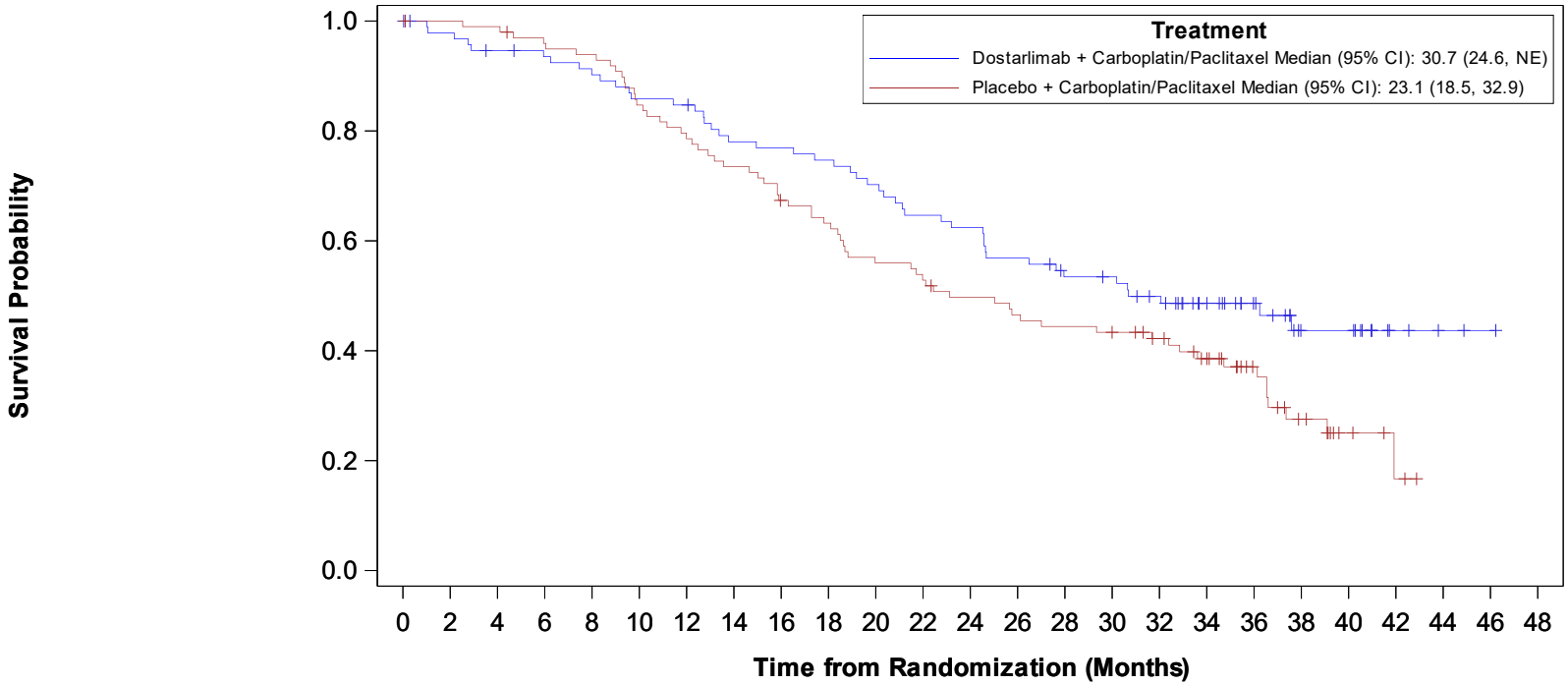
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	97(0)	96(0)	95(1)	90(5)	83(12)	78(17)	76(19)	74(21)	71(23)	70(24)	68(26)	67(27)	66(28)	62(32)	59(35)	51(42)	44(43)	36(45)	28(47)	25(47)	16(47)	7(48)	2(48)	0(49)	
Placebo + Carboplatin/Paclitaxel (N=184)	84(0)	82(1)	79(4)	75(8)	75(8)	72(11)	69(13)	61(21)	60(22)	54(27)	50(31)	47(34)	46(35)	45(36)	44(37)	41(39)	37(39)	29(39)	21(41)	16(41)	10(42)	5(42)	3(42)	2(42)	0(42)

NE = Not Estimable.
Program: f_2_0102_km_os_age.sas, Output: f_2_0102_km_os_age.rtf, Generated on: 23JUL2024 19:30,
Data Cutoff Date: 22SEP2023

Figure 2.0102 Graph of Kaplan Meier Curves of Overall Survival by Age Group
(ITT Analysis Set): MMRp/MSS Subjects

Age Group: >=65



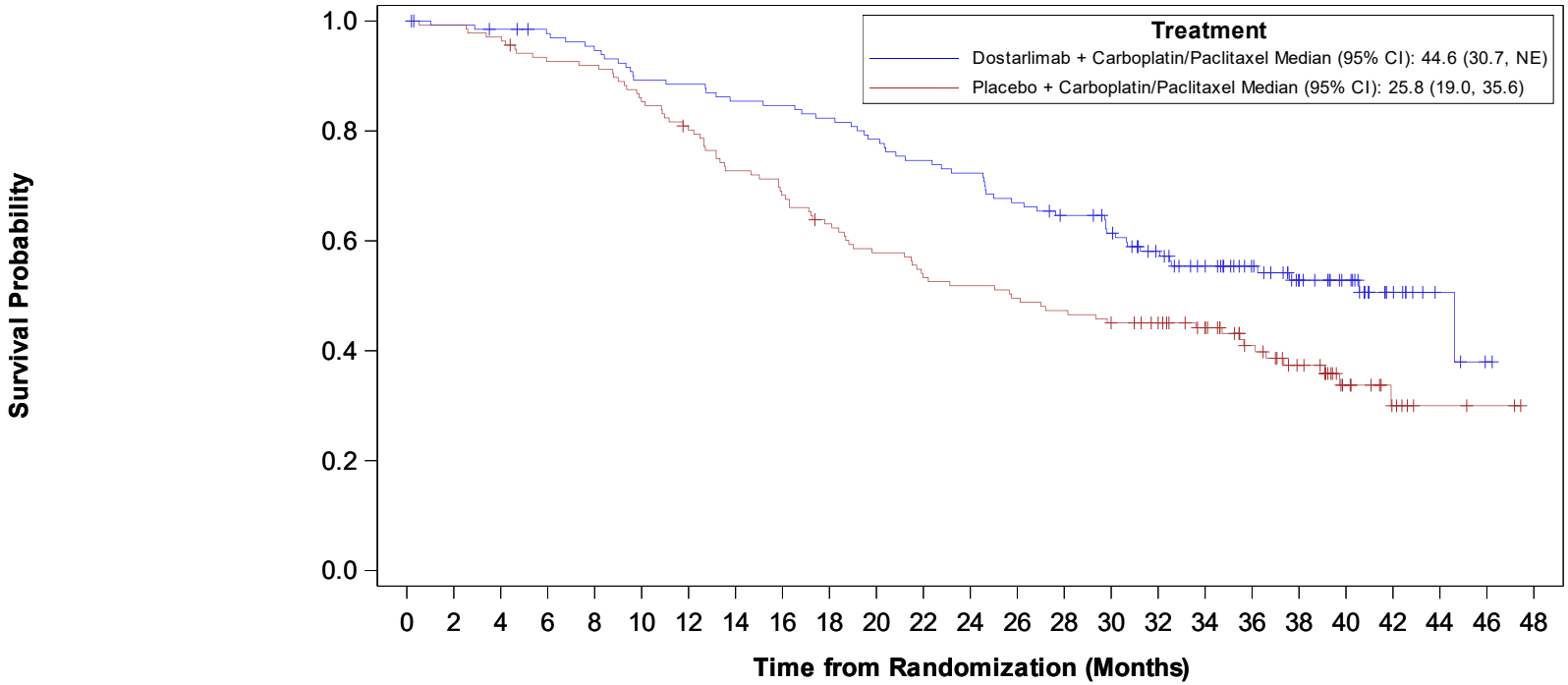
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	95(0)	91(2)	87(5)	85(6)	82(9)	78(13)	77(14)	70(20)	69(21)	67(23)	63(27)	58(32)	56(34)	51(39)	46(42)	45(42)	40(45)	31(46)	23(46)	13(48)	13(48)	4(48)	2(48)	1(48)	0(48)
Placebo + Carboplatin/Paclitaxel (N=184)	100(0)	99(0)	98(1)	94(4)	92(6)	83(15)	77(21)	72(26)	65(32)	61(36)	54(43)	51(46)	47(49)	44(52)	42(54)	40(55)	36(56)	30(59)	20(60)	12(65)	5(66)	2(67)	0(67)		

NE = Not Estimable.
Program: f_2_0102_km_os_age.sas, Output: f_2_0102_km_os_age.rtf, Generated on: 23JUL2024 19:30,
Data Cutoff Date: 22SEP2023

Figure 2.0202 Graph of Kaplan Meier Curves of Overall Survival by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: North America



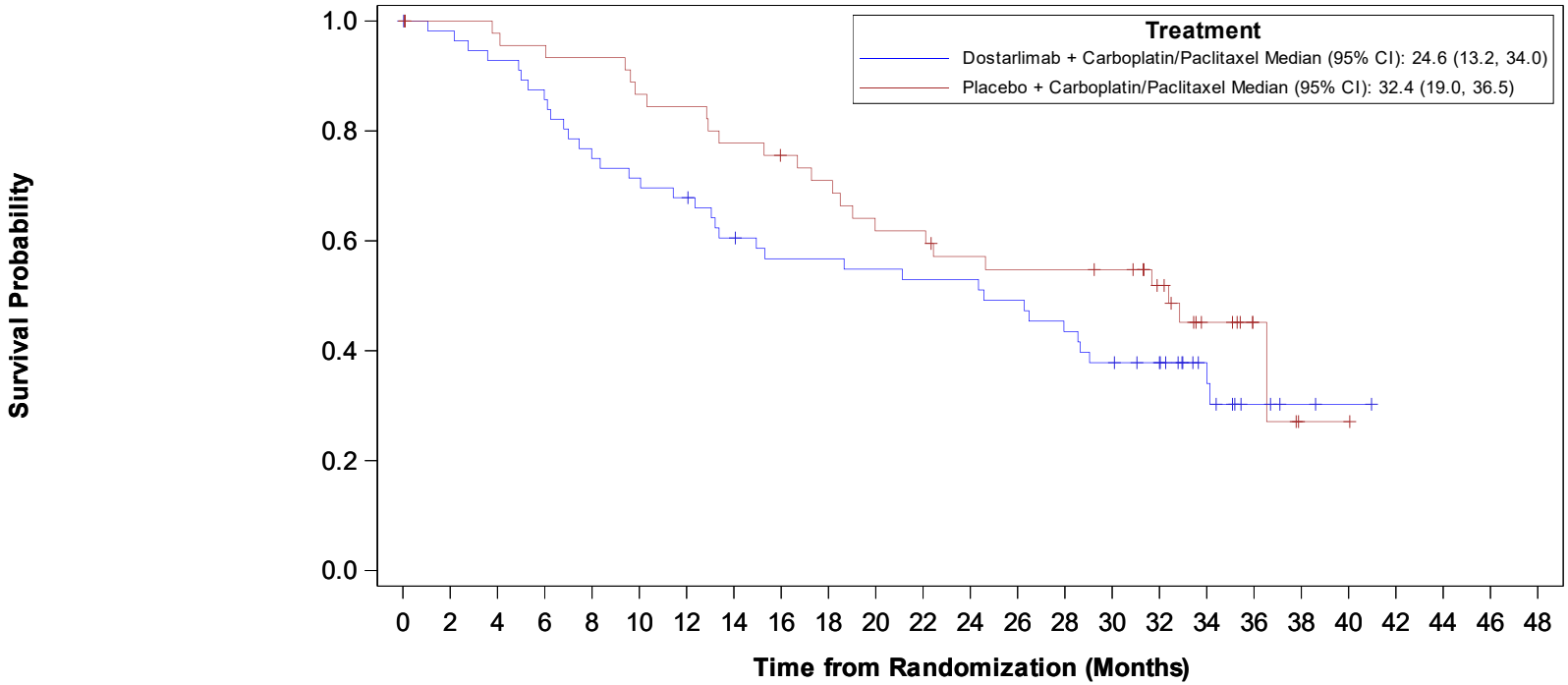
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	135(0) 132(1) 130(2) 127(3) 123(7) 116(14) 115(15) 111(19) 110(20) 107(23) 102(28) 97(33) 94(36) 87(43) 82(46) 76(50) 66(54) 57(57) 47(57) 36(59) 28(59) 11(60) 4(60) 1(61) 0(61)
Placebo + Carboplatin/Paclitaxel (N=184)	137(0) 136(1) 133(4) 126(10) 125(11) 116(20) 108(27) 98(37) 92(43) 84(50) 77(57) 71(63) 69(65) 66(68) 63(71) 59(74) 56(74) 49(75) 36(78) 27(81) 14(83) 7(84) 3(84) 2(84) 0(84)

NE = Not Estimable.
Program: f_2_0202_km_os_reg.sas, Output: f_2_0202_km_os_reg.rtf, Generated on: 23JUL2024 19:30,
Data Cutoff Date: 22SEP2023

Figure 2.0202 Graph of Kaplan Meier Curves of Overall Survival by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: Europe



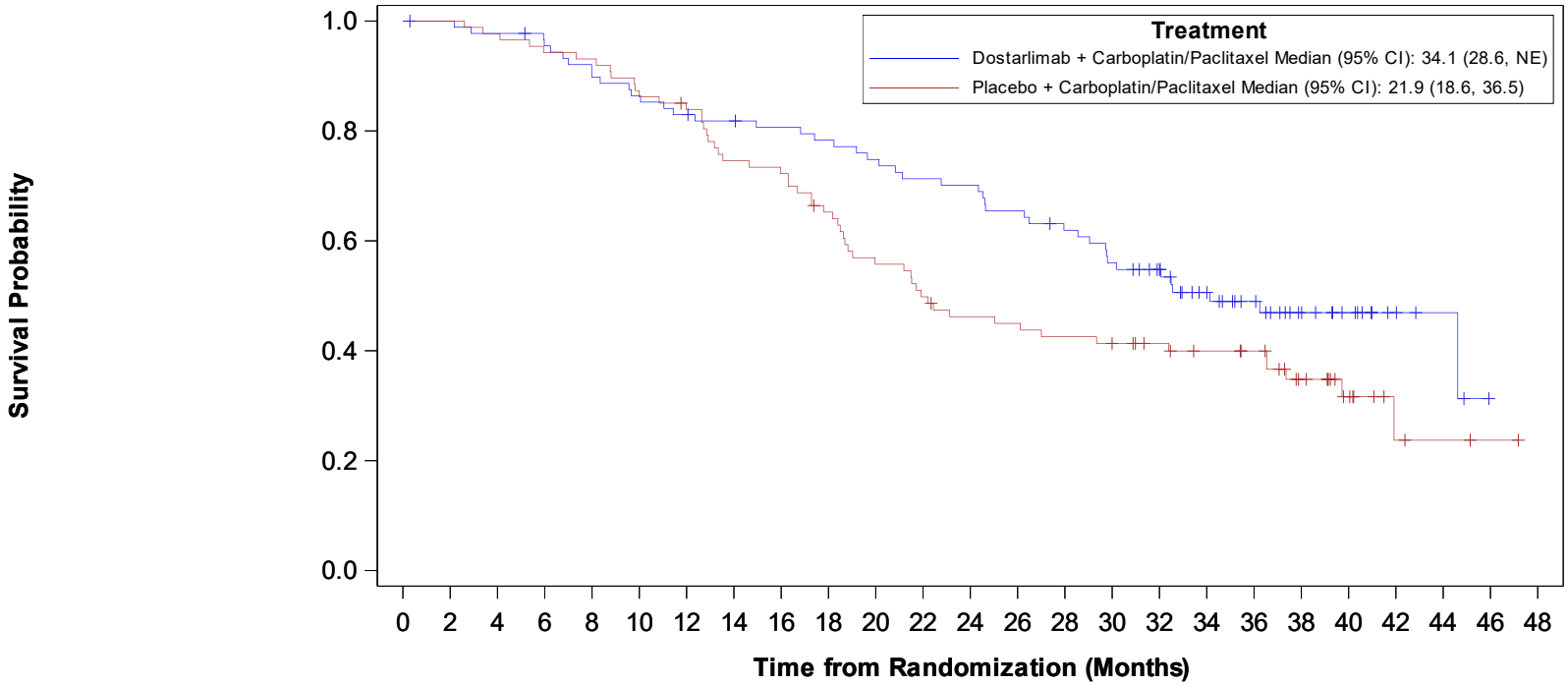
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	57(0)	55(1)	52(4)	48(8)	42(14)	40(16)	38(18)	33(22)	30(24)	30(24)	29(25)	28(26)	28(26)	26(28)	23(31)	20(34)	18(34)	10(34)	4(36)	2(36)	1(36)	0(36)		
Placebo + Carboplatin/Paclitaxel (N=184)	47(0)	45(0)	44(1)	43(2)	42(3)	39(6)	38(7)	35(10)	33(11)	31(13)	27(17)	27(17)	24(19)	23(20)	23(20)	22(20)	17(21)	10(23)	5(23)	1(25)	1(25)	0(25)		

NE = Not Estimable.
Program: f_2_0202_km_os_reg.sas, Output: f_2_0202_km_os_reg.rtf, Generated on: 23JUL2024 19:30,
Data Cutoff Date: 22SEP2023

Figure 2.0302 Graph of Kaplan Meier Curves of Overall Survival by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Recurrent



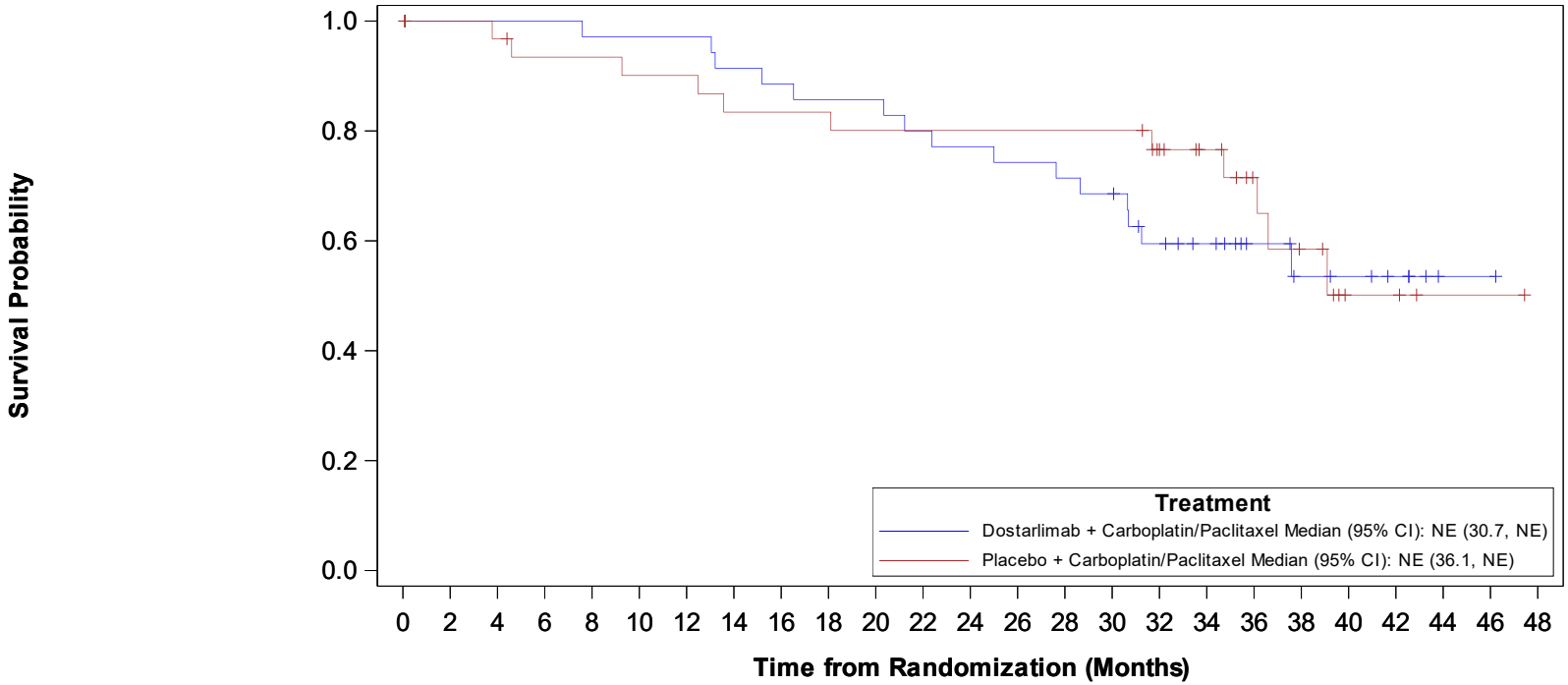
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	90(0)	89(0)	87(2)	84(4)	79(9)	76(12)	73(15)	71(16)	69(17)	67(19)	64(22)	61(25)	60(26)	56(30)	52(33)	47(38)	42(39)	32(42)	25(43)	17(44)	12(44)	5(44)	3(44)	0(45)	
Placebo + Carboplatin/Paclitaxel (N=184)	87(0)	87(0)	85(2)	82(5)	81(6)	75(12)	72(14)	64(22)	62(24)	55(30)	47(38)	42(43)	38(46)	37(47)	35(49)	33(50)	30(50)	27(51)	25(51)	17(54)	9(55)	3(56)	2(56)	1(56)	0(56)

NE = Not Estimable.
Program: f_2_0302_km_os_dstat.sas, Output: f_2_0302_km_os_dstat.rtf, Generated on: 23JUL2024 19:32,
Data Cutoff Date: 22SEP2023

Figure 2.0302 Graph of Kaplan Meier Curves of Overall Survival by Disease Status
(ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage III



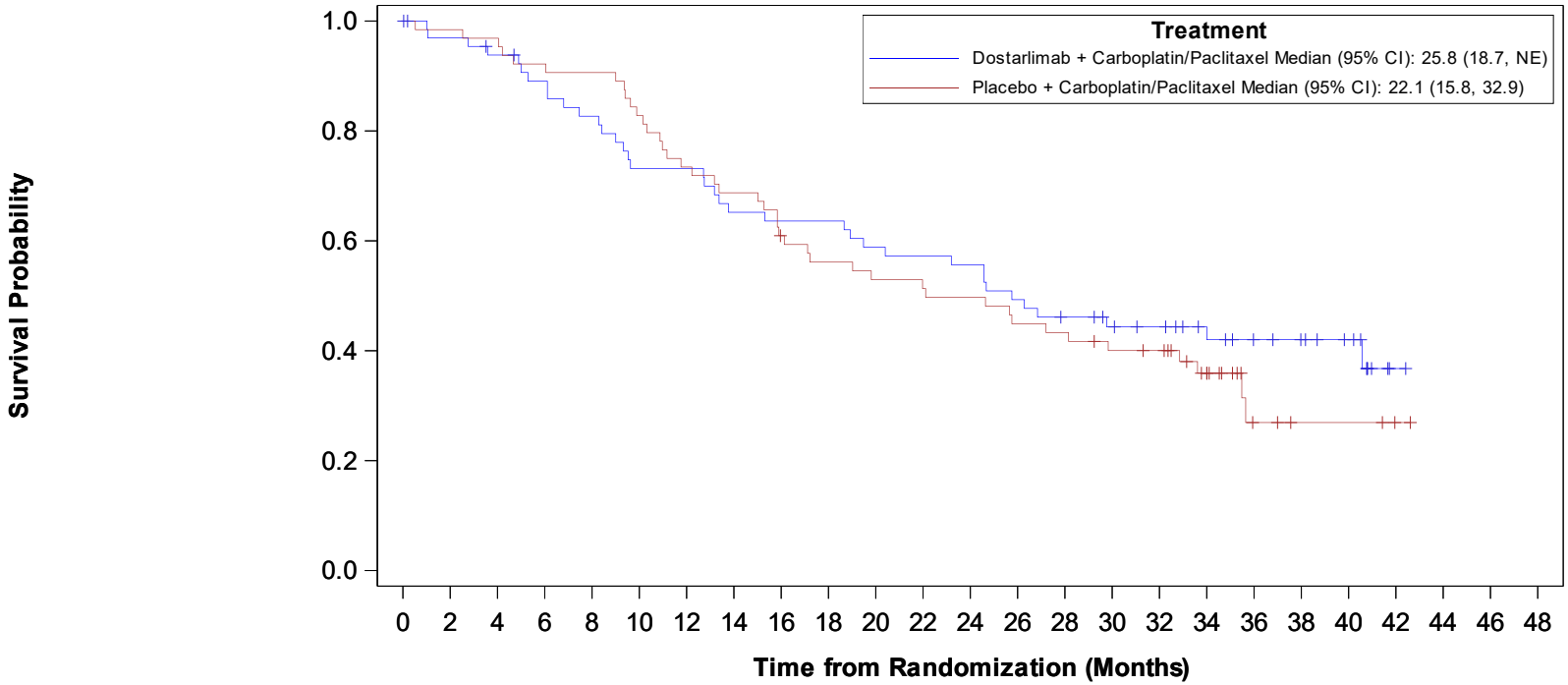
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	35(0)	35(0)	35(0)	35(0)	34(1)	34(1)	34(1)	32(3)	31(4)	30(5)	30(5)	28(7)	27(8)	26(9)	25(10)	24(11)	19(14)	16(14)	11(14)	8(15)	7(15)	5(15)	1(15)	1(15)	0(15)
Placebo + Carboplatin/Paclitaxel (N=184)	33(0)	31(0)	30(1)	28(2)	28(2)	27(3)	27(3)	25(5)	25(5)	25(5)	24(6)	24(6)	24(6)	24(6)	24(6)	24(6)	20(7)	16(7)	11(8)	8(10)	3(11)	3(11)	1(11)	1(11)	0(11)

NE = Not Estimable.
Program: f_2_0302_km_os_dstat.sas, Output: f_2_0302_km_os_dstat.rtf, Generated on: 23JUL2024 19:32,
Data Cutoff Date: 22SEP2023

Figure 2.0302 Graph of Kaplan Meier Curves of Overall Survival by Disease Status
(ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage IV



Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	67(0)	63(2)	60(4)	56(7)	52(11)	46(17)	46(17)	41(22)	40(23)	40(23)	37(26)	36(27)	35(28)	31(32)	28(34)	25(35)	23(35)	19(35)	15(36)	13(36)	10(36)	1(37)	0(37)
Placebo + Carboplatin/Paclitaxel (N=184)	64(0)	63(1)	62(2)	59(5)	58(6)	53(11)	47(17)	44(20)	38(25)	35(28)	33(30)	32(31)	31(32)	28(35)	27(36)	24(38)	23(38)	16(40)	5(42)	3(42)	3(42)	1(42)	0(42)

NE = Not Estimable.
Program: f_2_0302_km_os_dstat.sas, Output: f_2_0302_km_os_dstat.rtf, Generated on: 23JUL2024 19:32,
Data Cutoff Date: 22SEP2023

Table 1.0101 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
PFS		
Status [n (%)]		
Events observed	48 (49.5%)	41 (48.8%)
Disease progression	44 (45.4%)	41 (48.8%)
Death	4 (4.1%)	0
Censored	49 (50.5%)	43 (51.2%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	5.6 (4.2, 7.4)	5.7 (3.3, 7.8)
50%	9.9 (7.6, NE)	9.7 (7.8, NE)
75%	NE (NE, NE)	NE (NE, NE)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: REQ1032_T_1_0101_PFSB_AGE.sas, Output: REQ1032_T_1_0101_PFSB_AGE.rtf, Generated on: 09DEC2024 14:40, Data Cutoff Date: 22NOV2022

Table 1.0101 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	68.7% (57.7%, 77.4%)	74.7% (63.2%, 83.1%)
Month 9	57.0% (45.6%, 66.9%)	57.4% (44.8%, 68.1%)
Month 12	42.7% (31.4%, 53.4%)	46.0% (33.7%, 57.5%)
Month 18	39.4% (28.3%, 50.3%)	42.6% (30.4%, 54.2%)
Month 24	39.4% (28.3%, 50.3%)	38.2% (26.1%, 50.2%)
Month 30	39.4% (28.3%, 50.3%)	38.2% (26.1%, 50.2%)
Month 36	NE (NE, NE)	38.2% (26.1%, 50.2%)
Hazard ratio[b] (95% CI)	1.02 (0.668, 1.559)	
Hazard ratio[b] (96% CI)	1.02 (0.655, 1.591)	
p-value of 2-sided stratified log-rank test	0.9259	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: REQ1032_T_1_0101_PFSB_AGE.sas, Output: REQ1032_T_1_0101_PFSB_AGE.rtf, Generated on: 09DEC2024 14:40, Data Cutoff Date: 22NOV2022

Table 1.0101 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
PFS		
Status [n (%)]		
Events observed	50 (52.6%)	66 (66.0%)
Disease progression	46 (48.4%)	63 (63.0%)
Death	4 (4.2%)	3 (3.0%)
Censored	45 (47.4%)	34 (34.0%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	5.6 (5.3, 7.6)	5.4 (4.3, 6.8)
50%	9.9 (8.8, 19.1)	7.7 (7.0, 9.5)
75%	NE (21.0, NE)	14.8 (9.9, 22.4)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: REQ1032_T_1_0101_PFSB_AGE.sas, Output: REQ1032_T_1_0101_PFSB_AGE.rtf, Generated on: 09DEC2024 14:40, Data Cutoff Date: 22NOV2022

Table 1.0101 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	73.5% (62.6%, 81.7%)	68.5% (57.6%, 77.1%)
Month 9	60.2% (48.5%, 70.0%)	42.5% (31.8%, 52.9%)
Month 12	47.3% (35.7%, 58.1%)	29.4% (19.5%, 39.9%)
Month 18	39.5% (28.2%, 50.6%)	18.4% (10.0%, 28.7%)
Month 24	31.3% (20.2%, 43.0%)	13.1% (5.7%, 23.7%)
Month 30	31.3% (20.2%, 43.0%)	NE (NE, NE)
Month 36	NE (NE, NE)	NE (NE, NE)
Hazard ratio[b] (95% CI)	0.62 (0.423, 0.898)	
Hazard ratio[b] (96% CI)	0.62 (0.416, 0.915)	
p-value of 2-sided stratified log-rank test	0.0114	
p-value from Interaction Test[c]	0.1383	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: REQ1032_T_1_0101_PFSB_AGE.sas, Output: REQ1032_T_1_0101_PFSB_AGE.rtf, Generated on: 09DEC2024 14:40, Data Cutoff Date: 22NOV2022

Table 1.0102 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
PFS		
Status [n (%)]		
Events observed	62 (45.9%)	84 (61.3%)
Disease progression	61 (45.2%)	82 (59.9%)
Death	1 (0.7%)	2 (1.5%)
Censored	73 (54.1%)	53 (38.7%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	5.9 (5.4, 7.9)	5.5 (4.3, 6.9)
50%	11.7 (9.6, NE)	8.4 (7.6, 9.7)
75%	NE (NE, NE)	19.9 (12.0, NE)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: REQ1032_T_1_0102_PFSB_REG.sas, Output: REQ1032_T_1_0102_PFSB_REG.rtf, Generated on: 10DEC2024 09:01, Data Cutoff Date: 22NOV2022

Table 1.0102 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	74.2% (65.3%, 81.1%)	72.9% (64.0%, 79.9%)
Month 9	63.8% (54.3%, 71.9%)	47.9% (38.4%, 56.8%)
Month 12	48.4% (38.6%, 57.6%)	33.8% (25.0%, 42.8%)
Month 18	44.9% (35.1%, 54.2%)	25.9% (17.8%, 34.8%)
Month 24	41.7% (31.7%, 51.4%)	21.8% (14.0%, 30.7%)
Month 30	41.7% (31.7%, 51.4%)	21.8% (14.0%, 30.7%)
Month 36	NE (NE, NE)	21.8% (14.0%, 30.7%)
Hazard ratio[b] (95% CI)	0.61 (0.439, 0.855)	
Hazard ratio[b] (96% CI)	0.61 (0.432, 0.869)	
p-value of 2-sided stratified log-rank test	0.0037	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: REQ1032_T_1_0102_PFSB_REG.sas, Output: REQ1032_T_1_0102_PFSB_REG.rtf, Generated on: 10DEC2024 09:01, Data Cutoff Date: 22NOV2022

Table 1.0102 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
PFS		
Status [n (%)]		
Events observed	36 (63.2%)	23 (48.9%)
Disease progression	29 (50.9%)	22 (46.8%)
Death	7 (12.3%)	1 (2.1%)
Censored	21 (36.8%)	24 (51.1%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	5.5 (4.2, 6.2)	5.5 (3.9, 7.4)
50%	8.4 (5.8, 14.3)	9.5 (6.8, NE)
75%	19.1 (12.0, NE)	NE (20.0, NE)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: REQ1032_T_1_0102_PFSB_REG.sas, Output: REQ1032_T_1_0102_PFSB_REG.rtf, Generated on: 10DEC2024 09:01, Data Cutoff Date: 22NOV2022

Table 1.0102 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	64.1% (49.1%, 75.7%)	66.6% (50.1%, 78.7%)
Month 9	46.4% (31.8%, 59.7%)	52.9% (36.3%, 67.0%)
Month 12	36.7% (23.0%, 50.5%)	46.1% (29.5%, 61.2%)
Month 18	26.9% (14.9%, 40.5%)	42.3% (25.7%, 57.9%)
Month 24	20.4% (9.3%, 34.4%)	36.2% (19.1%, 53.6%)
Month 30	NE (NE, NE)	NE (NE, NE)
Month 36	NE (NE, NE)	NE (NE, NE)
Hazard ratio[b] (95% CI)	1.42 (0.818, 2.459)	
Hazard ratio[b] (96% CI)	1.42 (0.797, 2.524)	
p-value of 2-sided stratified log-rank test	0.2074	
p-value from Interaction Test[c]	0.0073	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: REQ1032_T_1_0102_PFSB_REG.sas, Output: REQ1032_T_1_0102_PFSB_REG.rtf, Generated on: 10DEC2024 09:01, Data Cutoff Date: 22NOV2022

Table 1.0103 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
PFS		
Status [n (%)]		
Events observed	43 (47.8%)	52 (59.8%)
Disease progression	43 (47.8%)	50 (57.5%)
Death	0	2 (2.3%)
Censored	47 (52.2%)	35 (40.2%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	5.6 (5.4, 7.4)	5.4 (4.2, 6.9)
50%	11.7 (7.9, 21.0)	7.8 (7.4, 9.3)
75%	NE (21.0, NE)	17.1 (11.7, NE)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: REQ1032_T_1_0103_PFSB_DSTAT.sas, Output: REQ1032_T_1_0103_PFSB_DSTAT.rtf, Generated on: 10DEC2024 09:03, Data Cutoff Date: 22NOV2022

Table 1.0103 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	70.5% (59.0%, 79.4%)	69.1% (57.5%, 78.1%)
Month 9	57.1% (44.9%, 67.6%)	41.8% (30.3%, 52.9%)
Month 12	46.8% (34.6%, 58.2%)	31.5% (20.7%, 42.8%)
Month 18	43.3% (31.1%, 54.9%)	25.0% (14.8%, 36.6%)
Month 24	37.0% (24.9%, 49.0%)	25.0% (14.8%, 36.6%)
Month 30	37.0% (24.9%, 49.0%)	NE (NE, NE)
Month 36	NE (NE, NE)	NE (NE, NE)
Hazard ratio[b] (95% CI)	0.70 (0.467, 1.054)	
Hazard ratio[b] (96% CI)	0.70 (0.458, 1.074)	
p-value of 2-sided stratified log-rank test	0.0853	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: REQ1032_T_1_0103_PFSB_DSTAT.sas, Output: REQ1032_T_1_0103_PFSB_DSTAT.rtf, Generated on: 10DEC2024 09:03, Data Cutoff Date: 22NOV2022

Table 1.0103 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
PFS		
Status [n (%)]		
Events observed	15 (42.9%)	15 (45.5%)
Disease progression	15 (42.9%)	15 (45.5%)
Death	0	0
Censored	20 (57.1%)	18 (54.5%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	7.6 (4.5, 9.7)	6.9 (1.6, 9.5)
50%	11.7 (9.0, NE)	15.2 (7.6, NE)
75%	NE (NE, NE)	NE (22.4, NE)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: REQ1032_T_1_0103_PFSB_DSTAT.sas, Output: REQ1032_T_1_0103_PFSB_DSTAT.rtf, Generated on: 10DEC2024 09:03, Data Cutoff Date: 22NOV2022

Table 1.0103 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	76.9% (57.5%, 88.3%)	81.4% (60.9%, 91.8%)
Month 9	69.7% (49.7%, 83.0%)	69.8% (48.5%, 83.6%)
Month 12	47.4% (28.3%, 64.3%)	54.3% (33.7%, 70.9%)
Month 18	47.4% (28.3%, 64.3%)	46.5% (26.9%, 64.0%)
Month 24	47.4% (28.3%, 64.3%)	38.8% (18.5%, 58.7%)
Month 30	47.4% (28.3%, 64.3%)	38.8% (18.5%, 58.7%)
Month 36	NE (NE, NE)	38.8% (18.5%, 58.7%)
Hazard ratio[b] (95% CI)	0.90 (0.432, 1.861)	
Hazard ratio[b] (96% CI)	0.90 (0.417, 1.927)	
p-value of 2-sided stratified log-rank test	0.7783	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: REQ1032_T_1_0103_PFSB_DSTAT.sas, Output: REQ1032_T_1_0103_PFSB_DSTAT.rtf, Generated on: 10DEC2024 09:03, Data Cutoff Date: 22NOV2022

Table 1.0103 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
PFS		
Status [n (%)]		
Events observed	40 (59.7%)	40 (62.5%)
Disease progression	32 (47.8%)	39 (60.9%)
Death	8 (11.9%)	1 (1.6%)
Censored	27 (40.3%)	24 (37.5%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	5.3 (2.8, 7.4)	5.4 (1.6, 7.0)
50%	9.6 (7.4, 14.6)	8.8 (7.0, 11.6)
75%	NE (14.6, NE)	19.9 (9.9, NE)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: REQ1032_T_1_0103_PFSB_DSTAT.sas, Output: REQ1032_T_1_0103_PFSB_DSTAT.rtf, Generated on: 10DEC2024 09:03, Data Cutoff Date: 22NOV2022

Table 1.0103 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on BICR by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

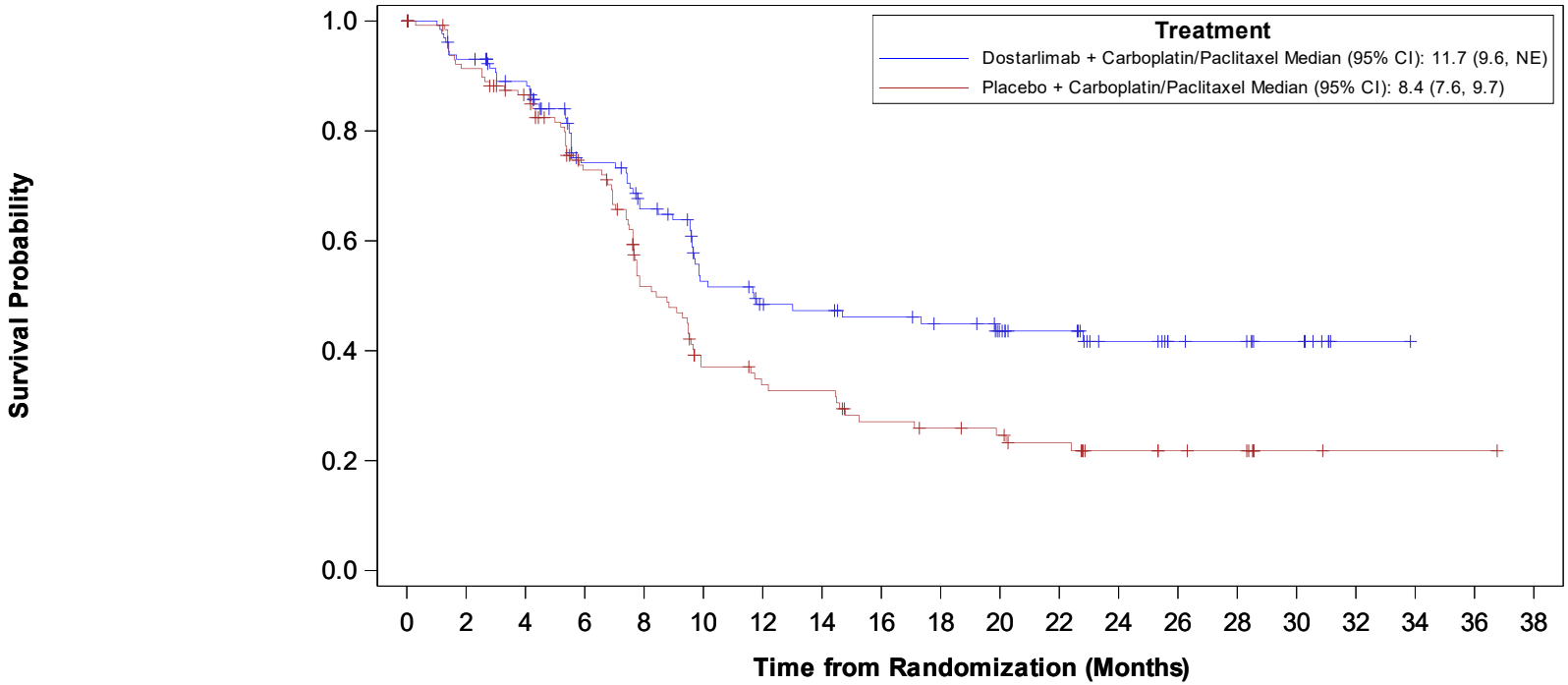
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	68.7% (55.3%, 78.8%)	69.6% (56.0%, 79.7%)
Month 9	54.2% (40.6%, 66.0%)	49.1% (34.9%, 61.7%)
Month 12	41.3% (28.4%, 53.7%)	35.3% (22.1%, 48.6%)
Month 18	30.8% (19.0%, 43.4%)	27.1% (15.0%, 40.7%)
Month 24	27.0% (15.1%, 40.4%)	17.0% (6.9%, 30.7%)
Month 30	27.0% (15.1%, 40.4%)	17.0% (6.9%, 30.7%)
Month 36	NE (NE, NE)	NE (NE, NE)
Hazard ratio[b] (95% CI)	0.85 (0.545, 1.315)	
Hazard ratio[b] (96% CI)	0.85 (0.534, 1.343)	
p-value of 2-sided stratified log-rank test	0.4575	
p-value from Interaction Test[c]	0.7363	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: REQ1032_T_1_0103_PFSB_DSTAT.sas, Output: REQ1032_T_1_0103_PFSB_DSTAT.rtf, Generated on: 10DEC2024 09:03, Data Cutoff Date: 22NOV2022

Figure 1.0102 Graph of Kaplan Meier Curves of Progression Free Survival - RECIST v1.1 based on BICR by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: North America



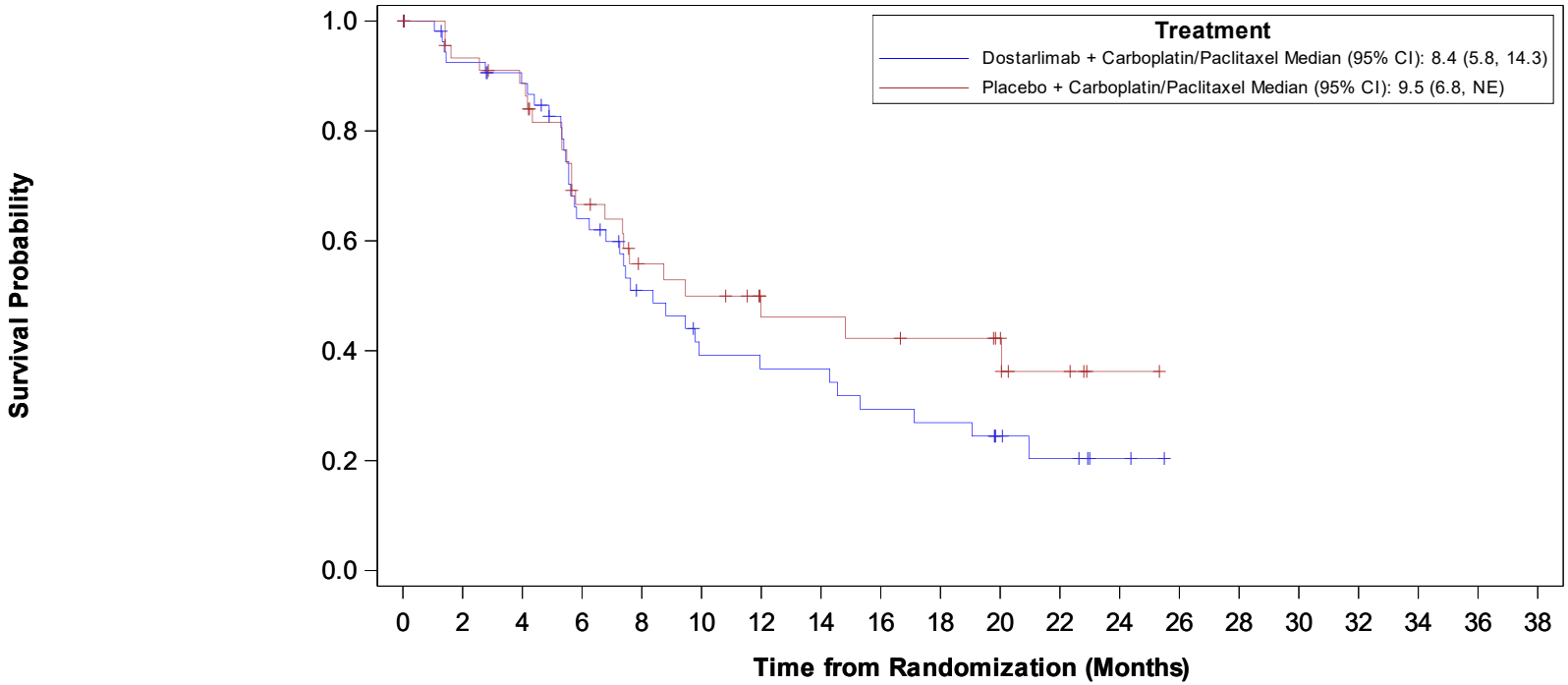
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	135(0)	120(9)	109(14)	81(31)	69(40)	51(53)	44(57)	42(58)	39(59)	36(60)	30(61)	26(61)	18(62)	13(62)	12(62)	8(62)	1(62)	0(62)		
Placebo + Carboplatin/Paclitaxel (N=184)	137(0)	116(11)	105(17)	82(33)	54(56)	35(71)	31(74)	30(75)	23(80)	21(81)	19(82)	16(83)	11(84)	9(84)	8(84)	2(84)	1(84)	1(84)	1(84)	0(84)

NE = Not Estimable.
Program: REQ1032_F_1_0102_PFSB_REG.sas, Output: REQ1032_F_1_0102_PFSB_REG.rtf, Generated on: 11DEC2024 11:50,
Data Cutoff Date: 22NOV2022

Figure 1.0102 Graph of Kaplan Meier Curves of Progression Free Survival - RECIST v1.1 based on BICR by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: Europe



Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	57(0)	49(4)	45(6)	31(18)	22(24)	16(29)	15(30)	15(30)	12(33)	11(34)	7(35)	5(36)	2(36)	0(36)
Placebo + Carboplatin/Paclitaxel (N=184)	47(0)	41(3)	38(5)	26(14)	19(18)	17(20)	12(21)	12(21)	11(22)	10(22)	8(22)	4(23)	1(23)	0(23)

NE = Not Estimable.
Program: REQ1032_F_1_0102_PFSB_REG.sas, Output: REQ1032_F_1_0102_PFSB_REG.rtf, Generated on: 11DEC2024 11:50,
Data Cutoff Date: 22NOV2022

Table 1.0201 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Analysis by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
PFS		
Status [n (%)]		
Events observed	58 (59.8%)	54 (64.3%)
Disease progression	55 (56.7%)	53 (63.1%)
Death	3 (3.1%)	1 (1.2%)
Censored	39 (40.2%)	30 (35.7%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	5.7 (4.9, 7.5)	5.6 (3.3, 7.6)
50%	9.8 (7.9, 14.4)	9.8 (7.7, 12.2)
75%	30.3 (17.6, NE)	NE (14.4, NE)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: REQ1032_T_1_0201_PFSI_AGE.sas, Output: REQ1032_T_1_0201_PFSI_AGE.rtf, Generated on: 09DEC2024 15:21, Data Cutoff Date: 22NOV2022

Table 1.0201 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Analysis by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	74.4% (63.8%, 82.4%)	71.1% (59.5%, 79.9%)
Month 9	57.1% (45.7%, 66.9%)	54.7% (42.8%, 65.2%)
Month 12	42.9% (32.0%, 53.4%)	39.7% (28.5%, 50.5%)
Month 18	34.3% (24.0%, 44.9%)	30.1% (20.1%, 40.7%)
Month 24	29.7% (19.8%, 40.3%)	28.4% (18.6%, 39.0%)
Month 30	26.4% (16.1%, 37.8%)	25.3% (15.2%, 36.6%)
Month 36	NE (NE, NE)	25.3% (15.2%, 36.6%)
Hazard ratio[b] (95% CI)	0.92 (0.629, 1.336)	
Hazard ratio[b] (96% CI)	0.92 (0.618, 1.361)	
p-value of 2-sided stratified log-rank test	0.6498	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: REQ1032_T_1_0201_PFSI_AGE.sas, Output: REQ1032_T_1_0201_PFSI_AGE.rtf, Generated on: 09DEC2024 15:21, Data Cutoff Date: 22NOV2022

Table 1.0201 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Analysis by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
PFS		
Status [n (%)]		
Events observed	58 (61.1%)	76 (76.0%)
Disease progression	54 (56.8%)	72 (72.0%)
Death	4 (4.2%)	4 (4.0%)
Censored	37 (38.9%)	24 (24.0%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	5.7 (4.8, 7.7)	5.5 (4.3, 5.9)
50%	9.9 (7.8, 17.1)	7.8 (7.4, 8.2)
75%	25.7 (19.8, NE)	12.0 (9.8, 22.8)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: REQ1032_T_1_0201_PFSI_AGE.sas, Output: REQ1032_T_1_0201_PFSI_AGE.rtf, Generated on: 09DEC2024 15:21, Data Cutoff Date: 22NOV2022

Table 1.0201 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Analysis by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	72.4% (61.4%, 80.8%)	65.5% (54.7%, 74.4%)
Month 9	58.4% (46.9%, 68.3%)	39.5% (29.2%, 49.6%)
Month 12	44.0% (32.9%, 54.6%)	22.6% (14.4%, 32.0%)
Month 18	37.4% (26.8%, 48.0%)	16.3% (9.3%, 25.1%)
Month 24	27.0% (17.0%, 37.9%)	9.8% (3.9%, 18.9%)
Month 30	22.5% (11.9%, 35.2%)	6.5% (1.7%, 16.3%)
Month 36	0 (NE, NE)	NE (NE, NE)
Hazard ratio[b] (95% CI)	0.62 (0.439, 0.883)	
Hazard ratio[b] (96% CI)	0.62 (0.432, 0.898)	
p-value of 2-sided stratified log-rank test	0.0076	
p-value from Interaction Test[c]	0.1344	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: REQ1032_T_1_0201_PFSI_AGE.sas, Output: REQ1032_T_1_0201_PFSI_AGE.rtf, Generated on: 09DEC2024 15:21, Data Cutoff Date: 22NOV2022

Table 1.0202 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Assessment by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
PFS		
Status [n (%)]		
Events observed	77 (57.0%)	98 (71.5%)
Disease progression	75 (55.6%)	95 (69.3%)
Death	2 (1.5%)	3 (2.2%)
Censored	58 (43.0%)	39 (28.5%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	7.5 (5.6, 8.3)	5.5 (4.3, 5.9)
50%	11.9 (9.7, 17.6)	7.9 (7.6, 9.7)
75%	30.3 (22.8, NE)	14.8 (11.7, 28.3)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: REQ1032_T_1_0202_PFSI_REG.sas, Output: REQ1032_T_1_0202_PFSI_REG.rtf, Generated on: 09DEC2024 15:23, Data Cutoff Date: 22NOV2022

Table 1.0202 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Assessment by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	79.1% (70.6%, 85.4%)	67.1% (58.1%, 74.6%)
Month 9	64.8% (55.3%, 72.7%)	44.9% (35.8%, 53.5%)
Month 12	49.2% (39.6%, 58.0%)	30.1% (22.1%, 38.6%)
Month 18	40.2% (30.9%, 49.2%)	22.2% (15.1%, 30.1%)
Month 24	33.5% (24.5%, 42.6%)	18.7% (12.0%, 26.6%)
Month 30	28.8% (19.4%, 38.9%)	15.6% (9.1%, 23.6%)
Month 36	0 (NE, NE)	15.6% (9.1%, 23.6%)
Hazard ratio[b] (95% CI)	0.63 (0.466, 0.855)	
Hazard ratio[b] (96% CI)	0.63 (0.459, 0.868)	
p-value of 2-sided stratified log-rank test	0.0028	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: REQ1032_T_1_0202_PFSI_REG.sas, Output: REQ1032_T_1_0202_PFSI_REG.rtf, Generated on: 09DEC2024 15:23, Data Cutoff Date: 22NOV2022

Table 1.0202 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Assessment by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
PFS		
Status [n (%)]		
Events observed	39 (68.4%)	32 (68.1%)
Disease progression	34 (59.6%)	30 (63.8%)
Death	5 (8.8%)	2 (4.3%)
Censored	18 (31.6%)	15 (31.9%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	4.9 (2.8, 5.7)	5.7 (3.0, 7.6)
50%	7.5 (5.7, 9.6)	9.5 (7.4, 12.0)
75%	19.1 (9.6, NE)	15.2 (11.5, NE)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: REQ1032_T_1_0202_PFSI_REG.sas, Output: REQ1032_T_1_0202_PFSI_REG.rtf, Generated on: 09DEC2024 15:23, Data Cutoff Date: 22NOV2022

Table 1.0202 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Assessment by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	60.1% (45.1%, 72.2%)	71.2% (54.9%, 82.5%)
Month 9	40.9% (27.0%, 54.2%)	51.6% (35.5%, 65.5%)
Month 12	30.1% (17.9%, 43.3%)	31.9% (18.5%, 46.2%)
Month 18	25.8% (14.4%, 38.8%)	24.6% (12.8%, 38.4%)
Month 24	14.8% (5.1%, 29.2%)	18.4% (6.8%, 34.4%)
Month 30	NE (NE, NE)	NE (NE, NE)
Month 36	NE (NE, NE)	NE (NE, NE)
Hazard ratio[b] (95% CI)	1.20 (0.737, 1.945)	
Hazard ratio[b] (96% CI)	1.20 (0.720, 1.991)	
p-value of 2-sided stratified log-rank test	0.4462	
p-value from Interaction Test[c]	0.0215	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: REQ1032_T_1_0202_PFSI_REG.sas, Output: REQ1032_T_1_0202_PFSI_REG.rtf, Generated on: 09DEC2024 15:23, Data Cutoff Date: 22NOV2022

Table 1.0203 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Analysis by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
PFS		
Status [n (%)]		
Events observed	58 (64.4%)	64 (73.6%)
Disease progression	58 (64.4%)	60 (69.0%)
Death	0	4 (4.6%)
Censored	32 (35.6%)	23 (26.4%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	5.6 (4.9, 7.6)	5.5 (4.2, 7.4)
50%	9.6 (7.7, 11.9)	7.9 (7.6, 9.6)
75%	25.7 (14.3, NE)	12.0 (9.8, 23.0)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: REQ1032_T_1_0203_PFSI_DSTAT.sas, Output: REQ1032_T_1_0203_PFSI_DSTAT.rtf, Generated on: 09DEC2024 15:23, Data Cutoff Date: 22NOV2022

Table 1.0203 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Analysis by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	72.3% (61.0%, 80.8%)	66.8% (55.1%, 76.0%)
Month 9	53.5% (41.7%, 63.9%)	41.4% (30.3%, 52.1%)
Month 12	36.6% (25.8%, 47.4%)	22.5% (13.8%, 32.5%)
Month 18	32.4% (22.0%, 43.1%)	16.9% (9.4%, 26.2%)
Month 24	25.5% (15.9%, 36.3%)	15.0% (7.8%, 24.3%)
Month 30	18.6% (9.0%, 30.9%)	NE (NE, NE)
Month 36	NE (NE, NE)	NE (NE, NE)
Hazard ratio[b] (95% CI)	0.76 (0.529, 1.084)	
Hazard ratio[b] (96% CI)	0.76 (0.520, 1.102)	
p-value of 2-sided stratified log-rank test	0.1289	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: REQ1032_T_1_0203_PFSI_DSTAT.sas, Output: REQ1032_T_1_0203_PFSI_DSTAT.rtf, Generated on: 09DEC2024 15:23, Data Cutoff Date: 22NOV2022

Table 1.0203 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Analysis by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
PFS		
Status [n (%)]		
Events observed	17 (48.6%)	15 (45.5%)
Disease progression	17 (48.6%)	15 (45.5%)
Death	0	0
Censored	18 (51.4%)	18 (54.5%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	9.0 (4.5, 9.7)	7.6 (3.0, 11.7)
50%	14.4 (9.6, NE)	22.8 (9.5, NE)
75%	33.8 (NE, NE)	NE (22.8, NE)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: REQ1032_T_1_0203_PFSI_DSTAT.sas, Output: REQ1032_T_1_0203_PFSI_DSTAT.rtf, Generated on: 09DEC2024 15:23, Data Cutoff Date: 22NOV2022

Table 1.0203 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Analysis by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	83.8% (65.3%, 92.9%)	77.6% (56.8%, 89.3%)
Month 9	73.3% (53.6%, 85.7%)	73.8% (52.6%, 86.6%)
Month 12	52.4% (33.1%, 68.5%)	54.3% (33.8%, 71.0%)
Month 18	44.3% (25.7%, 61.4%)	50.5% (30.3%, 67.6%)
Month 24	44.3% (25.7%, 61.4%)	42.1% (20.5%, 62.3%)
Month 30	44.3% (25.7%, 61.4%)	31.5% (10.5%, 55.3%)
Month 36	0 (NE, NE)	31.5% (10.5%, 55.3%)
Hazard ratio[b] (95% CI)	1.02 (0.502, 2.081)	
Hazard ratio[b] (96% CI)	1.02 (0.485, 2.153)	
p-value of 2-sided stratified log-rank test	0.9508	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: REQ1032_T_1_0203_PFSI_DSTAT.sas, Output: REQ1032_T_1_0203_PFSI_DSTAT.rtf, Generated on: 09DEC2024 15:23, Data Cutoff Date: 22NOV2022

Table 1.0203 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Analysis by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
PFS		
Status [n (%)]		
Events observed	41 (61.2%)	51 (79.7%)
Disease progression	34 (50.7%)	50 (78.1%)
Death	7 (10.4%)	1 (1.6%)
Censored	26 (38.8%)	13 (20.3%)
Estimates for PFS (months)		
Quartile (95% CI)[a]		
25%	5.6 (3.0, 7.4)	5.4 (2.9, 6.6)
50%	9.9 (7.4, 17.6)	7.7 (6.7, 9.9)
75%	22.8 (17.6, NE)	14.8 (10.8, 22.8)

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: REQ1032_T_1_0203_PFSI_DSTAT.sas, Output: REQ1032_T_1_0203_PFSI_DSTAT.rtf, Generated on: 09DEC2024 15:23, Data Cutoff Date: 22NOV2022

Table 1.0203 Kaplan Meier Analysis of Progression Free Survival - RECIST v1.1 based on Investigator Analysis by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

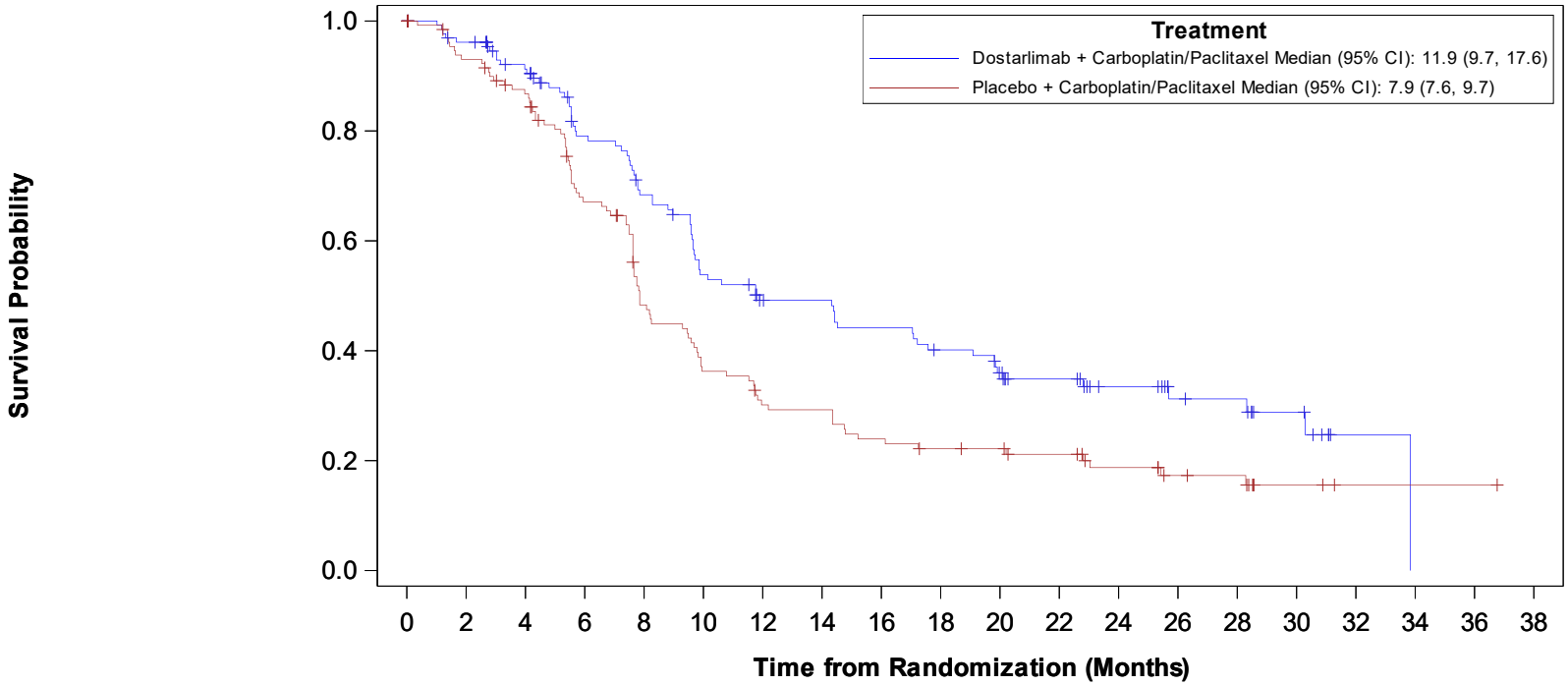
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS probability (95% CI) at		
Month 6	69.5% (56.0%, 79.6%)	65.8% (52.4%, 76.2%)
Month 9	55.3% (41.6%, 67.0%)	41.3% (28.6%, 53.5%)
Month 12	48.1% (34.8%, 60.3%)	30.5% (19.2%, 42.6%)
Month 18	36.1% (23.6%, 48.7%)	17.9% (9.3%, 28.9%)
Month 24	24.5% (13.4%, 37.3%)	13.3% (5.7%, 24.0%)
Month 30	24.5% (13.4%, 37.3%)	8.9% (2.3%, 21.0%)
Month 36	NE (NE, NE)	NE (NE, NE)
Hazard ratio[b] (95% CI)	0.68 (0.451, 1.032)	
Hazard ratio[b] (96% CI)	0.68 (0.442, 1.053)	
p-value of 2-sided stratified log-rank test	0.0696	
p-value from Interaction Test[c]	0.6040	

Note: PFS: Progression-Free Survival.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: REQ1032_T_1_0203_PFSI_DSTAT.sas, Output: REQ1032_T_1_0203_PFSI_DSTAT.rtf, Generated on: 09DEC2024 15:23, Data Cutoff Date: 22NOV2022

Figure 1.0202 Graph of Kaplan Meier Curves of Progression Free Survival - RECIST v1.1 based on Investigator Assessment by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: North America



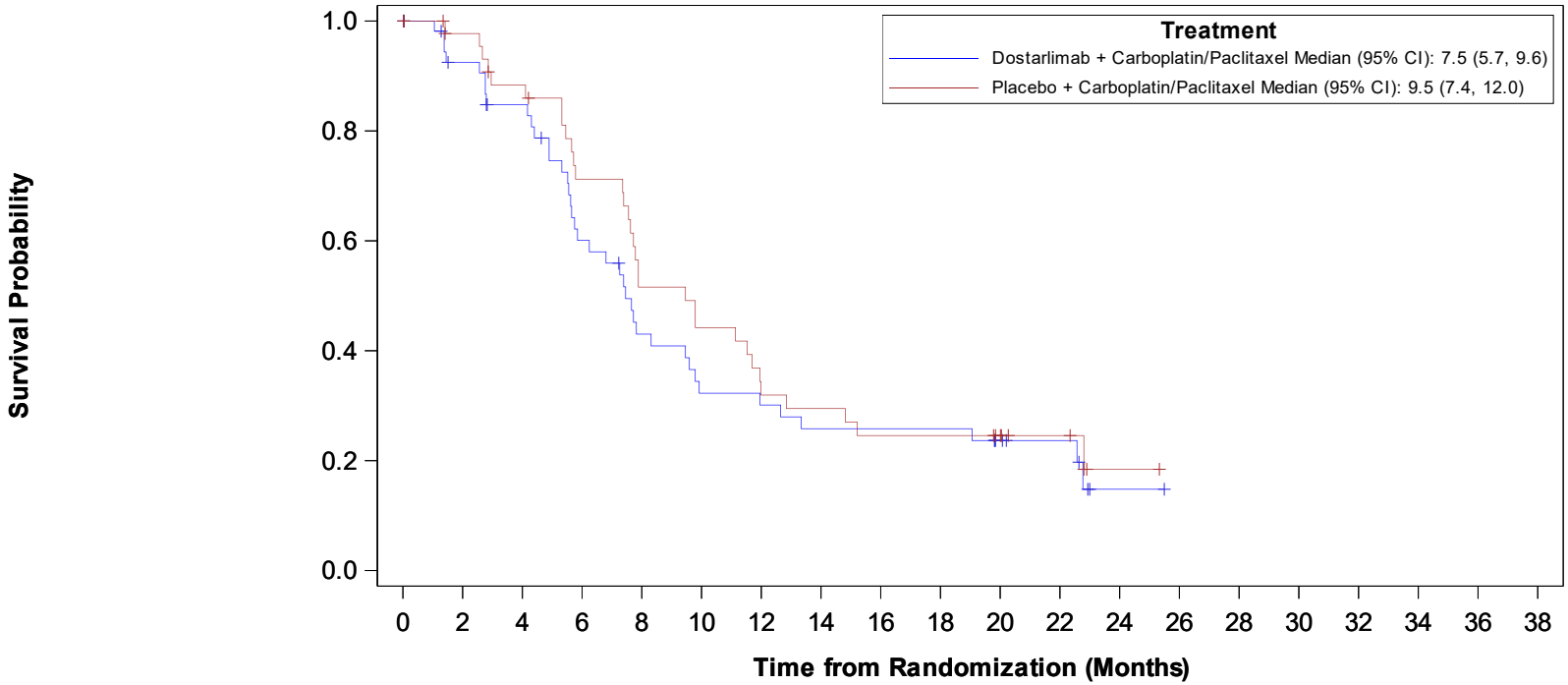
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	135(0)	124(5)	111(11)	89(25)	76(37)	59(53)	50(58)	49(58)	44(63)	39(67)	33(71)	27(72)	20(73)	14(74)	13(74)	8(75)	1(76)	0(77)		
Placebo + Carboplatin/Paclitaxel (N=184)	137(0)	120(9)	109(17)	81(41)	56(63)	42(77)	34(84)	33(85)	27(91)	24(93)	23(93)	20(94)	15(96)	11(97)	10(97)	3(98)	1(98)	1(98)	1(98)	0(98)

NE = Not Estimable.
Program: REQ1032_F_1_0202_PFSI_REG.sas, Output: REQ1032_F_1_0202_PFSI_REG.rtf, Generated on: 11DEC2024 11:47,
Data Cutoff Date: 22NOV2022

Figure 1.0202 Graph of Kaplan Meier Curves of Progression Free Survival - RECIST v1.1 based on Investigator Assessment by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: Europe



Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	57(0)	48(4)	42(8)	29(20)	20(28)	15(33)	14(34)	12(36)	12(36)	12(36)	8(37)	6(37)	1(39)	0(39)
Placebo + Carboplatin/Paclitaxel (N=184)	47(0)	42(1)	37(5)	29(12)	21(20)	18(23)	13(28)	12(29)	10(31)	10(31)	8(31)	5(31)	1(32)	0(32)

NE = Not Estimable.
Program: REQ1032_F_1_0202_PFSI_REG.sas, Output: REQ1032_F_1_0202_PFSI_REG.rtf, Generated on: 11DEC2024 11:47,
Data Cutoff Date: 22NOV2022

Table 2.0702 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
PFS2		
Status [n (%)]		
Events observed	51 (52.6%)	48 (57.1%)
Disease progression	32 (33.0%)	35 (41.7%)
Death	19 (19.6%)	13 (15.5%)
Censored	46 (47.4%)	36 (42.9%)
Estimates for PFS2 (months)		
Quartile (95% CI)[a]		
25%	11.9 (7.6, 15.1)	10.9 (8.6, 12.9)
50%	28.6 (18.7, 40.7)	20.3 (13.4, 31.6)
75%	NE (40.7, NE)	NE (NE, NE)

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_2_0702_km_pfs2_age.sas, Output: t_2_0702_km_pfs2_age.rtf, Generated on: 23JUL2024 19:28, Data Cutoff Date: 22SEP2023

Table 2.0702 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS2 probability (95% CI) at		
Month 6	90.4% (82.4%, 94.9%)	87.7% (78.3%, 93.2%)
Month 9	78.6% (68.8%, 85.6%)	84.0% (74.0%, 90.4%)
Month 12	74.2% (64.0%, 81.9%)	68.7% (57.3%, 77.6%)
Month 18	61.5% (50.7%, 70.7%)	51.8% (40.3%, 62.2%)
Month 24	54.4% (43.4%, 64.0%)	43.9% (32.7%, 54.5%)
Month 30	48.3% (37.5%, 58.3%)	41.2% (30.2%, 51.8%)
Month 36	43.9% (33.1%, 54.2%)	38.3% (27.5%, 49.0%)
Hazard ratio[b] (95% CI)	0.85 (0.568, 1.268)	
Hazard ratio[b] (96% CI)	0.85 (0.557, 1.293)	
p-value of 2-sided stratified log-rank test	0.4224	

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_2_0702_km_pfs2_age.sas, Output: t_2_0702_km_pfs2_age.rtf, Generated on: 23JUL2024 19:28, Data Cutoff Date: 22SEP2023

Table 2.0702 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
PFS2		
Status [n (%)]		
Events observed	52 (54.7%)	73 (73.0%)
Disease progression	30 (31.6%)	52 (52.0%)
Death	22 (23.2%)	21 (21.0%)
Censored	43 (45.3%)	27 (27.0%)
Estimates for PFS2 (months)		
Quartile (95% CI)[a]		
25%	12.0 (8.5, 15.0)	10.3 (8.3, 11.2)
50%	22.1 (16.9, 37.6)	15.2 (12.9, 21.4)
75%	NE (38.4, NE)	36.1 (24.6, NE)

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_2_0702_km_pfs2_age.sas, Output: t_2_0702_km_pfs2_age.rtf, Generated on: 23JUL2024 19:28, Data Cutoff Date: 22SEP2023

Table 2.0702 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS2 probability (95% CI) at		
Month 6	92.3% (84.6%, 96.3%)	91.8% (84.3%, 95.8%)
Month 9	84.1% (74.7%, 90.3%)	82.5% (73.4%, 88.7%)
Month 12	74.7% (64.1%, 82.5%)	63.9% (53.6%, 72.6%)
Month 18	57.5% (46.3%, 67.3%)	44.1% (34.1%, 53.7%)
Month 24	47.5% (36.5%, 57.8%)	34.4% (25.1%, 44.0%)
Month 30	43.8% (32.9%, 54.1%)	30.1% (21.3%, 39.5%)
Month 36	39.8% (29.1%, 50.2%)	25.8% (17.2%, 35.2%)
Hazard ratio[b] (95% CI)	0.70 (0.491, 1.008)	
Hazard ratio[b] (96% CI)	0.70 (0.482, 1.026)	
p-value of 2-sided stratified log-rank test	0.0542	
p-value from Interaction Test[c]	0.6325	

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_2_0702_km_pfs2_age.sas, Output: t_2_0702_km_pfs2_age.rtf, Generated on: 23JUL2024 19:28, Data Cutoff Date: 22SEP2023

Table 2.0802 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
PFS2		
Status [n (%)]		
Events observed	62 (45.9%)	91 (66.4%)
Disease progression	43 (31.9%)	65 (47.4%)
Death	19 (14.1%)	26 (19.0%)
Censored	73 (54.1%)	46 (33.6%)
Estimates for PFS2 (months)		
Quartile (95% CI)[a]		
25%	15.0 (12.0, 20.1)	10.0 (8.3, 11.0)
50%	32.6 (24.6, NE)	15.5 (13.4, 22.6)
75%	NE (NE, NE)	NE (33.6, NE)

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_2_0802_km_pfs2_reg.sas, Output: t_2_0802_km_pfs2_reg.rtf, Generated on: 23JUL2024 19:29, Data Cutoff Date: 22SEP2023

Table 2.0802 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS2 probability (95% CI) at		
Month 6	95.3% (89.8%, 97.9%)	88.0% (81.2%, 92.5%)
Month 9	87.9% (80.8%, 92.5%)	80.5% (72.7%, 86.3%)
Month 12	82.1% (74.1%, 87.8%)	64.4% (55.6%, 71.9%)
Month 18	67.5% (58.2%, 75.1%)	46.5% (37.8%, 54.8%)
Month 24	61.2% (51.8%, 69.3%)	38.6% (30.3%, 46.9%)
Month 30	55.8% (46.3%, 64.3%)	34.7% (26.6%, 42.9%)
Month 36	49.9% (40.3%, 58.7%)	31.7% (23.7%, 39.9%)
Hazard ratio[b] (95% CI)	0.57 (0.415, 0.795)	
Hazard ratio[b] (96% CI)	0.57 (0.409, 0.808)	
p-value of 2-sided stratified log-rank test	0.0007	

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_2_0802_km_pfs2_reg.sas, Output: t_2_0802_km_pfs2_reg.rtf, Generated on: 23JUL2024 19:29, Data Cutoff Date: 22SEP2023

Table 2.0802 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
PFS2		
Status [n (%)]		
Events observed	41 (71.9%)	30 (63.8%)
Disease progression	19 (33.3%)	22 (46.8%)
Death	22 (38.6%)	8 (17.0%)
Censored	16 (28.1%)	17 (36.2%)
Estimates for PFS2 (months)		
Quartile (95% CI)[a]		
25%	6.9 (5.3, 10.6)	11.5 (9.8, 13.1)
50%	14.6 (10.6, 19.6)	18.7 (12.9, 30.2)
75%	29.0 (19.6, NE)	NE (22.7, NE)

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_2_0802_km_pfs2_reg.sas, Output: t_2_0802_km_pfs2_reg.rtf, Generated on: 23JUL2024 19:29, Data Cutoff Date: 22SEP2023

Table 2.0802 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS2 probability (95% CI) at		
Month 6	82.1% (69.4%, 90.0%)	95.6% (83.4%, 98.9%)
Month 9	66.1% (52.1%, 76.8%)	91.1% (78.0%, 96.6%)
Month 12	57.1% (43.2%, 68.9%)	71.1% (55.5%, 82.1%)
Month 18	42.1% (28.9%, 54.6%)	50.7% (35.3%, 64.2%)
Month 24	28.7% (17.3%, 41.0%)	38.7% (24.4%, 52.7%)
Month 30	24.9% (14.3%, 36.9%)	36.2% (22.3%, 50.3%)
Month 36	24.9% (14.3%, 36.9%)	29.9% (16.6%, 44.5%)
Hazard ratio[b] (95% CI)	1.36 (0.832, 2.216)	
Hazard ratio[b] (96% CI)	1.36 (0.813, 2.268)	
p-value of 2-sided stratified log-rank test	0.2193	
p-value from Interaction Test[c]	0.0038	

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_2_0802_km_pfs2_reg.sas, Output: t_2_0802_km_pfs2_reg.rtf, Generated on: 23JUL2024 19:29, Data Cutoff Date: 22SEP2023

Table 2.0902 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
PFS2		
Status [n (%)]		
Events observed	50 (55.6%)	59 (67.8%)
Disease progression	29 (32.2%)	43 (49.4%)
Death	21 (23.3%)	16 (18.4%)
Censored	40 (44.4%)	28 (32.2%)
Estimates for PFS2 (months)		
Quartile (95% CI)[a]		
25%	12.4 (8.0, 14.9)	10.0 (8.6, 12.8)
50%	24.6 (17.4, 40.6)	15.5 (13.0, 21.3)
75%	NE (40.6, NE)	NE (23.1, NE)

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0902_km_pfs2_dstat.sas, Output: t_2_0902_km_pfs2_dstat.rtf, Generated on: 23JUL2024 19:30, Data Cutoff Date: 22SEP2023

Table 2.0902 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS2 probability (95% CI) at		
Month 6	93.2% (85.4%, 96.9%)	89.4% (80.6%, 94.3%)
Month 9	81.5% (71.6%, 88.2%)	83.5% (73.7%, 89.9%)
Month 12	75.6% (65.1%, 83.4%)	67.8% (56.6%, 76.6%)
Month 18	59.5% (48.2%, 69.2%)	44.1% (33.2%, 54.5%)
Month 24	50.6% (39.3%, 60.8%)	35.0% (24.8%, 45.4%)
Month 30	44.1% (33.1%, 54.5%)	29.8% (20.2%, 40.1%)
Month 36	39.7% (28.9%, 50.3%)	28.3% (18.9%, 38.5%)
Hazard ratio[b] (95% CI)	0.70 (0.477, 1.018)	
Hazard ratio[b] (96% CI)	0.70 (0.468, 1.036)	
p-value of 2-sided stratified log-rank test	0.0608	

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0902_km_pfs2_dstat.sas, Output: t_2_0902_km_pfs2_dstat.rtf, Generated on: 23JUL2024 19:30, Data Cutoff Date: 22SEP2023

Table 2.0902 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
PFS2		
Status [n (%)]		
Events observed	17 (48.6%)	16 (48.5%)
Disease progression	11 (31.4%)	9 (27.3%)
Death	6 (17.1%)	7 (21.2%)
Censored	18 (51.4%)	17 (51.5%)
Estimates for PFS2 (months)		
Quartile (95% CI)[a]		
25%	16.5 (10.6, 25.0)	13.2 (4.6, 23.5)
50%	37.6 (21.9, NE)	34.7 (13.6, NE)
75%	NE (37.6, NE)	NE (36.1, NE)

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0902_km_pfs2_dstat.sas, Output: t_2_0902_km_pfs2_dstat.rtf, Generated on: 23JUL2024 19:30, Data Cutoff Date: 22SEP2023

Table 2.0902 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS2 probability (95% CI) at		
Month 6	97.1% (81.4%, 99.6%)	89.9% (71.8%, 96.6%)
Month 9	91.3% (75.3%, 97.1%)	86.4% (67.7%, 94.7%)
Month 12	85.4% (68.3%, 93.6%)	76.0% (56.2%, 87.8%)
Month 18	72.7% (54.0%, 84.8%)	65.7% (45.6%, 79.9%)
Month 24	63.2% (44.3%, 77.2%)	58.8% (38.9%, 74.1%)
Month 30	56.9% (38.3%, 71.8%)	58.8% (38.9%, 74.1%)
Month 36	50.2% (32.0%, 66.0%)	49.2% (28.7%, 66.8%)
Hazard ratio[b] (95% CI)	0.85 (0.427, 1.712)	
Hazard ratio[b] (96% CI)	0.85 (0.413, 1.770)	
p-value of 2-sided stratified log-rank test	0.6573	

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0902_km_pfs2_dstat.sas, Output: t_2_0902_km_pfs2_dstat.rtf, Generated on: 23JUL2024 19:30, Data Cutoff Date: 22SEP2023

Table 2.0902 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
PFS2		
Status [n (%)]		
Events observed	36 (53.7%)	46 (71.9%)
Disease progression	22 (32.8%)	35 (54.7%)
Death	14 (20.9%)	11 (17.2%)
Censored	31 (46.3%)	18 (28.1%)
Estimates for PFS2 (months)		
Quartile (95% CI)[a]		
25%	9.0 (5.8, 14.1)	10.1 (6.7, 11.2)
50%	20.4 (14.1, 40.7)	14.8 (11.3, 22.0)
75%	NE (38.4, NE)	NE (22.6, NE)

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0902_km_pfs2_dstat.sas, Output: t_2_0902_km_pfs2_dstat.rtf, Generated on: 23JUL2024 19:30, Data Cutoff Date: 22SEP2023

Table 2.0902 Kaplan Meier Analysis of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

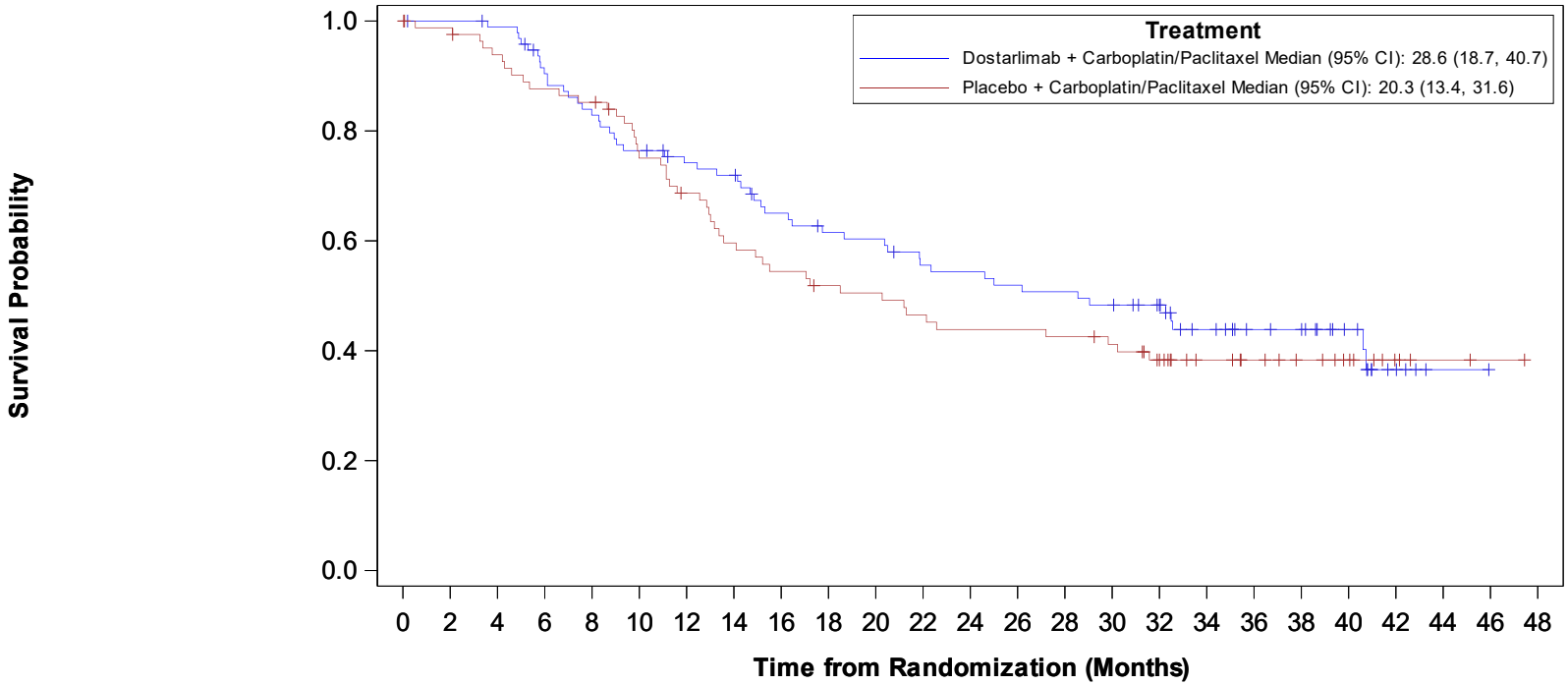
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
PFS2 probability (95% CI) at		
Month 6	85.4% (73.9%, 92.2%)	90.6% (80.3%, 95.7%)
Month 9	75.1% (62.1%, 84.2%)	81.3% (69.4%, 88.9%)
Month 12	66.4% (52.8%, 76.9%)	59.4% (46.3%, 70.2%)
Month 18	52.2% (38.6%, 64.1%)	43.6% (31.3%, 55.3%)
Month 24	44.7% (31.5%, 57.0%)	33.9% (22.6%, 45.6%)
Month 30	42.9% (29.8%, 55.2%)	30.5% (19.7%, 42.1%)
Month 36	40.7% (27.8%, 53.2%)	26.0% (15.5%, 37.8%)
Hazard ratio[b] (95% CI)	0.78 (0.506, 1.216)	
Hazard ratio[b] (96% CI)	0.78 (0.496, 1.241)	
p-value of 2-sided stratified log-rank test	0.2764	
p-value from Interaction Test[c]	0.9001	

Note: PFS2: Progression-Free Survival 2.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_2_0902_km_pfs2_dstat.sas, Output: t_2_0902_km_pfs2_dstat.rtf, Generated on: 23JUL2024 19:30, Data Cutoff Date: 22SEP2023

Figure 2.0502 Graph of Kaplan Meier Curves of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age Group: <65



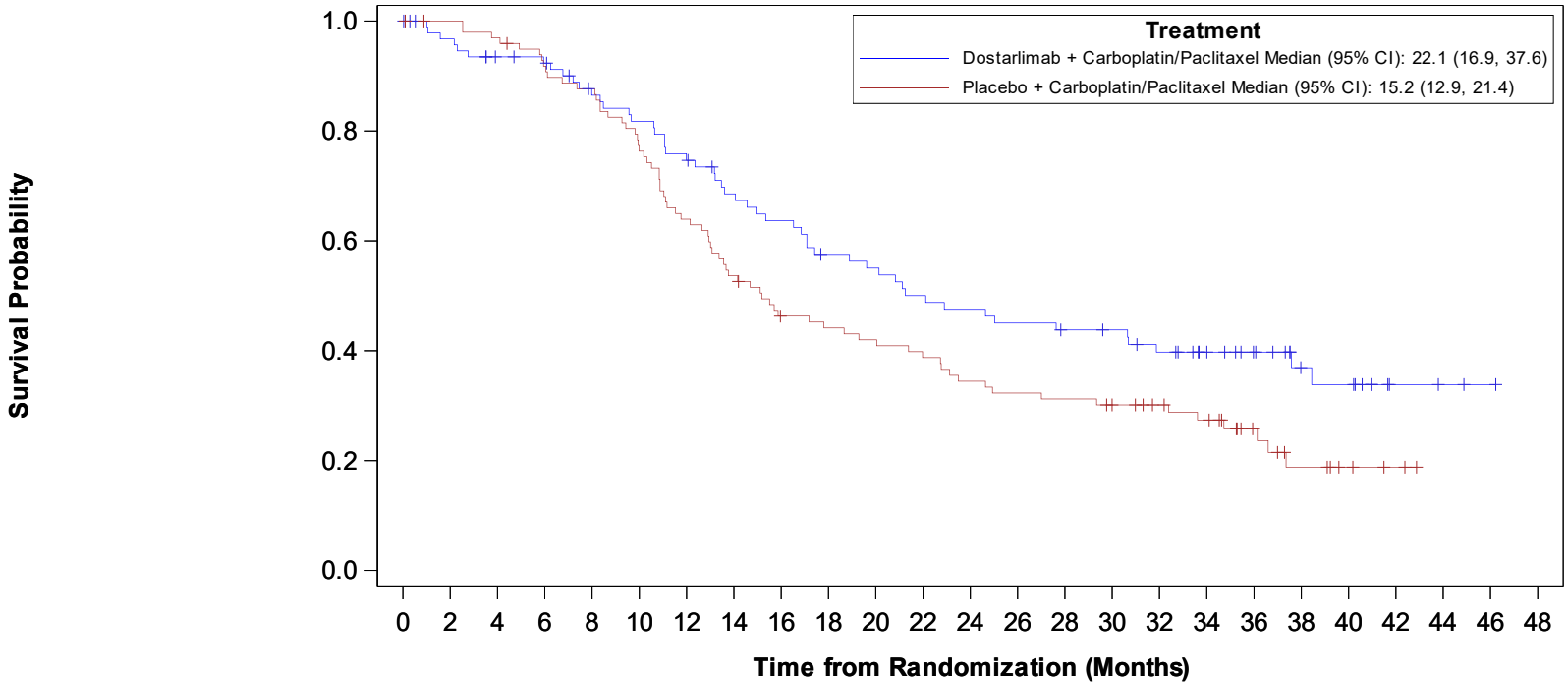
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	97(0)	96(0)	94(1)	84(9)	77(16)	71(22)	66(24)	64(26)	56(32)	52(35)	51(36)	46(40)	45(41)	43(43)	42(44)	40(46)	36(46)	27(49)	21(49)	20(49)	13(49)	5(51)	1(51)	0(51)	
Placebo + Carboplatin/Paclitaxel (N=184)	84(0)	81(1)	76(5)	71(10)	69(12)	59(20)	53(25)	46(32)	42(36)	39(38)	38(39)	35(42)	33(44)	33(44)	32(45)	30(46)	25(48)	18(48)	15(48)	12(48)	9(48)	4(48)	2(48)	1(48)	0(48)

NE = Not Estimable.
Program: f_2_0502_km_pfs2_age.sas, Output: f_2_0502_km_pfs2_age.rtf, Generated on: 23JUL2024 19:33,
Data Cutoff Date: 22SEP2023

Figure 2.0502 Graph of Kaplan Meier Curves of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Age Group: >=65



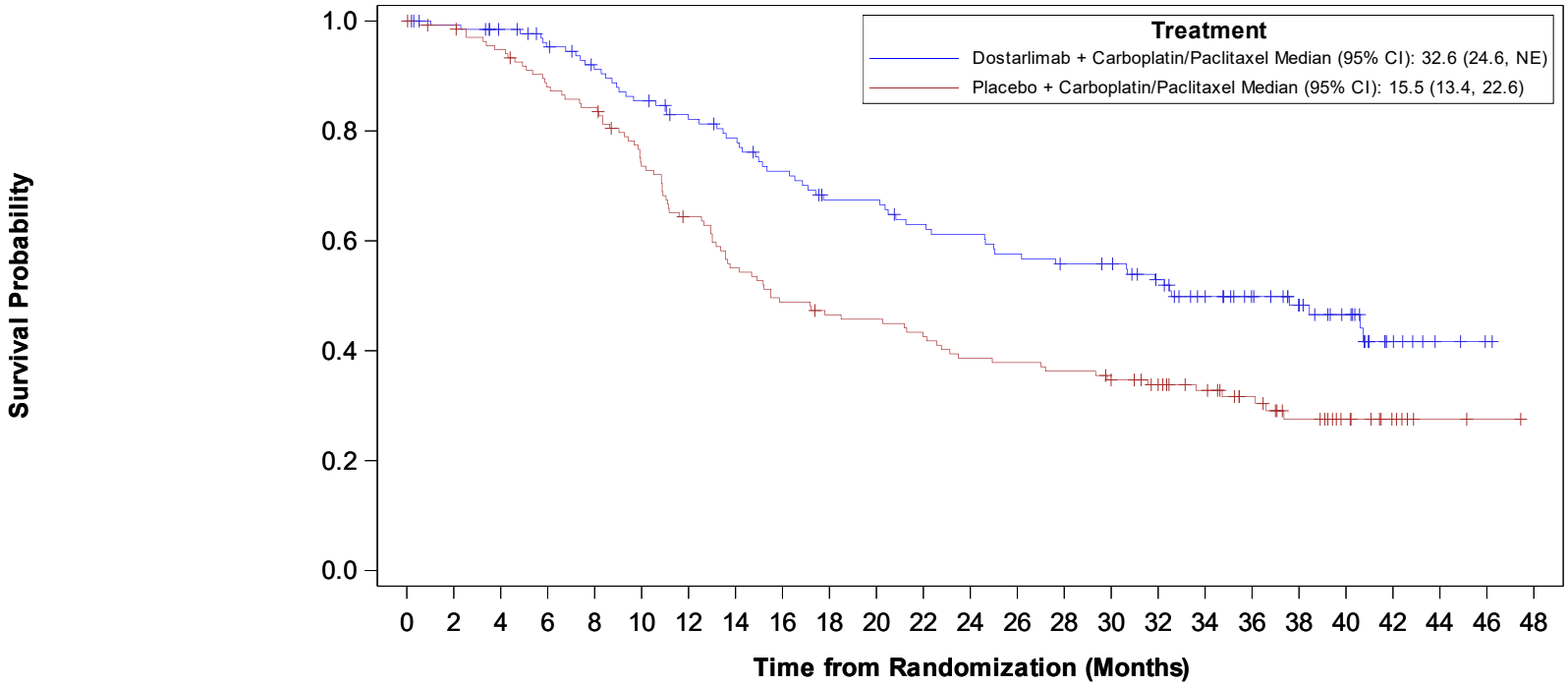
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	95(0)	89(3)	83(6)	81(7)	73(12)	69(16)	63(22)	56(27)	52(31)	46(36)	44(38)	40(42)	38(44)	36(46)	34(47)	33(47)	29(50)	24(50)	19(50)	12(51)	11(52)	3(52)	2(52)	1(52)	0(52)
Placebo + Carboplatin/Paclitaxel (N=184)	100(0)	98(0)	95(3)	89(8)	85(12)	74(23)	62(35)	52(45)	43(52)	41(54)	39(56)	36(59)	32(63)	30(65)	29(66)	26(67)	23(67)	20(69)	12(70)	7(73)	4(73)	2(73)	0(73)		

NE = Not Estimable.
Program: f_2_0502_km_pfs2_age.sas, Output: f_2_0502_km_pfs2_age.rtf, Generated on: 23JUL2024 19:33,
Data Cutoff Date: 22SEP2023

Figure 2.0602 Graph of Kaplan Meier Curves of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: North America



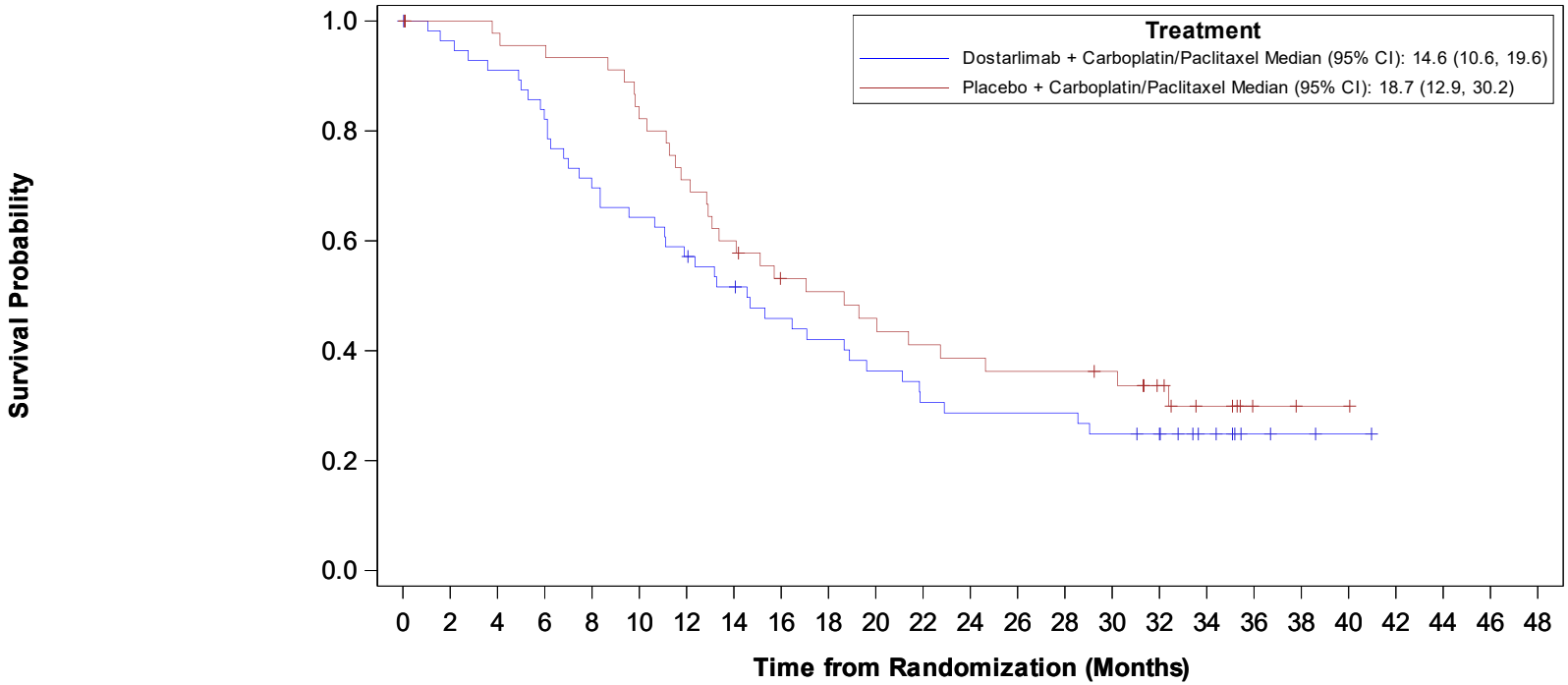
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	135(0)	131(1)	126(2)	119(6)	111(11)	104(18)	97(22)	92(26)	84(33)	76(39)	76(39)	70(44)	68(46)	64(50)	61(52)	60(52)	53(55)	44(58)	37(58)	30(59)	23(60)	8(62)	3(62)	1(62)	0(62)
Placebo + Carboplatin/Paclitaxel (N=184)	137(0)	134(1)	127(7)	117(16)	112(21)	96(35)	83(47)	71(59)	63(67)	59(70)	58(71)	54(75)	49(80)	48(81)	46(83)	42(85)	38(86)	32(87)	25(88)	18(91)	12(91)	6(91)	2(91)	1(91)	0(91)

NE = Not Estimable.
Program: f_2_0602_km_pfs2_reg.sas, Output: f_2_0602_km_pfs2_reg.rtf, Generated on: 23JUL2024 19:33,
Data Cutoff Date: 22SEP2023

Figure 2.0602 Graph of Kaplan Meier Curves of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Region (ITT Analysis Set): MMRp/MSS Subjects

Region: Europe



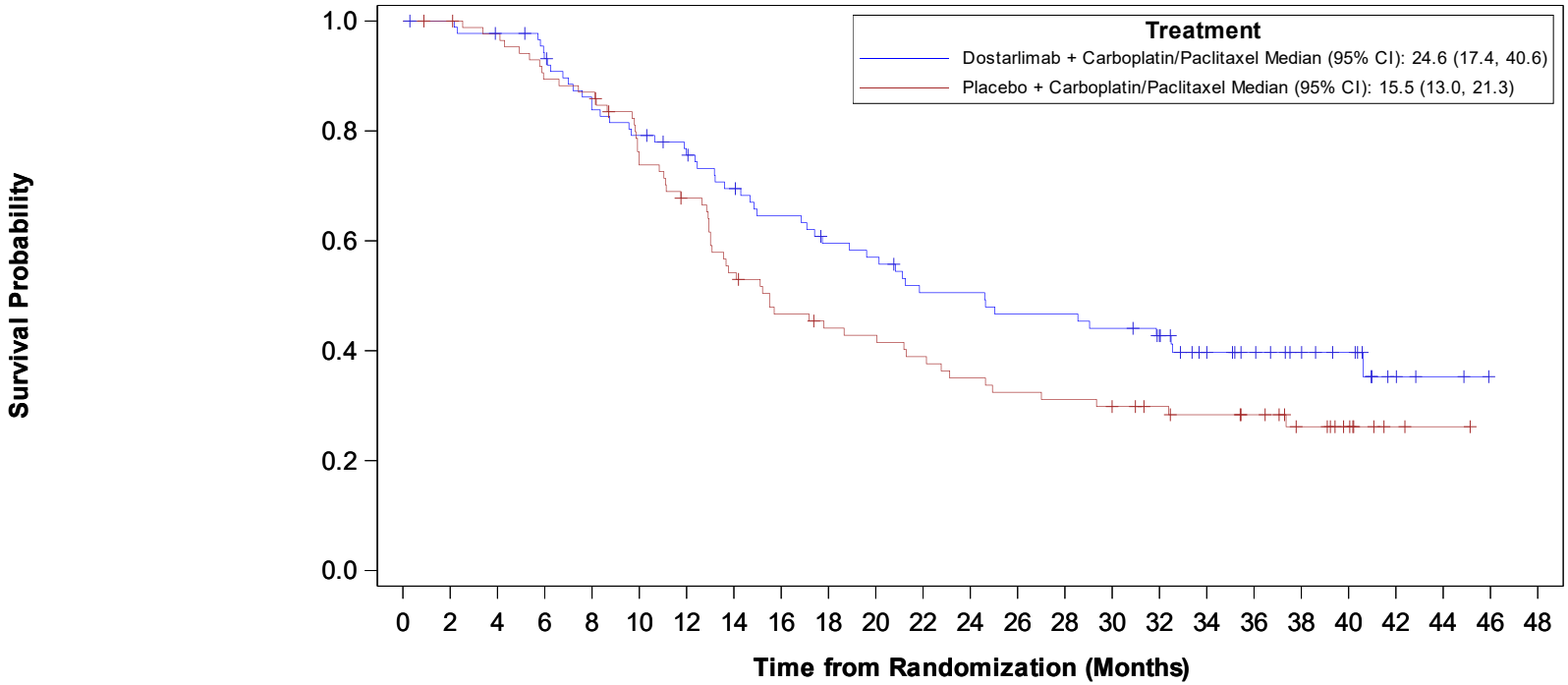
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	57(0)	54(2)	51(5)	46(10)	39(17)	36(20)	32(24)	28(27)	24(30)	22(32)	19(35)	16(38)	15(39)	15(39)	15(39)	13(41)	12(41)	7(41)	3(41)	2(41)	1(41)	0(41)
Placebo + Carboplatin/Paclitaxel (N=184)	47(0)	45(0)	44(1)	43(2)	42(3)	37(8)	32(13)	27(18)	22(21)	21(22)	19(24)	17(26)	16(27)	15(28)	15(28)	14(28)	10(29)	6(30)	2(30)	1(30)	1(30)	0(30)

NE = Not Estimable.
Program: f_2_0602_km_pfs2_reg.sas, Output: f_2_0602_km_pfs2_reg.rtf, Generated on: 23JUL2024 19:33,
Data Cutoff Date: 22SEP2023

Figure 2.0702 Graph of Kaplan Meier Curves of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Recurrent



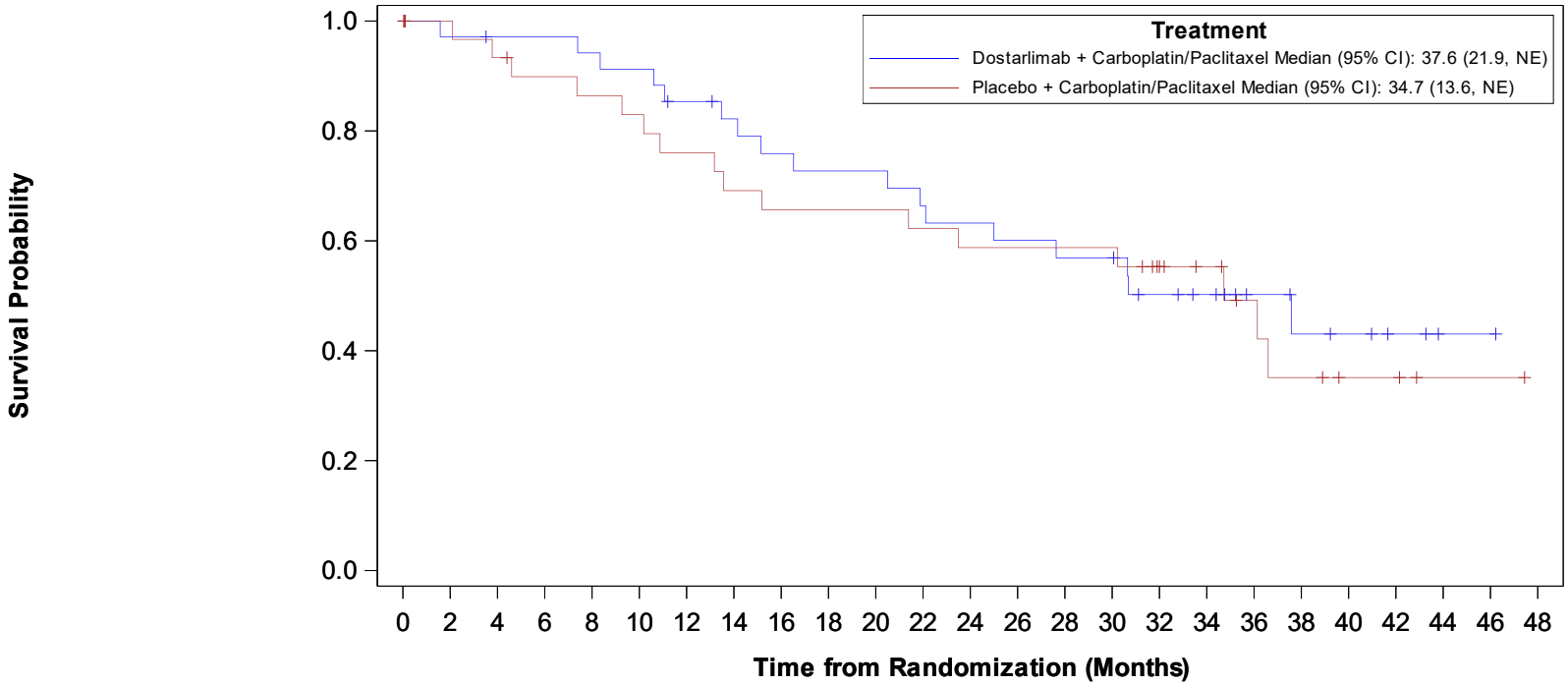
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	90(0)	89(0)	86(2)	81(6)	72(14)	68(18)	63(21)	57(26)	52(30)	47(34)	45(36)	39(41)	39(41)	36(44)	36(44)	34(46)	31(47)	23(49)	19(49)	15(49)	12(49)	4(50)	2(50)	0(50)
Placebo + Carboplatin/Paclitaxel (N=184)	87(0)	86(0)	83(2)	76(9)	74(11)	61(22)	55(27)	44(38)	37(44)	34(46)	33(47)	30(50)	27(53)	25(55)	24(56)	22(57)	20(57)	18(58)	16(58)	11(59)	7(59)	2(59)	1(59)	0(59)

NE = Not Estimable.
Program: f_2_0702_km_pfs2_dstat.sas, Output: f_2_0702_km_pfs2_dstat.rtf, Generated on: 23JUL2024 19:32,
Data Cutoff Date: 22SEP2023

Figure 2.0702 Graph of Kaplan Meier Curves of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage III



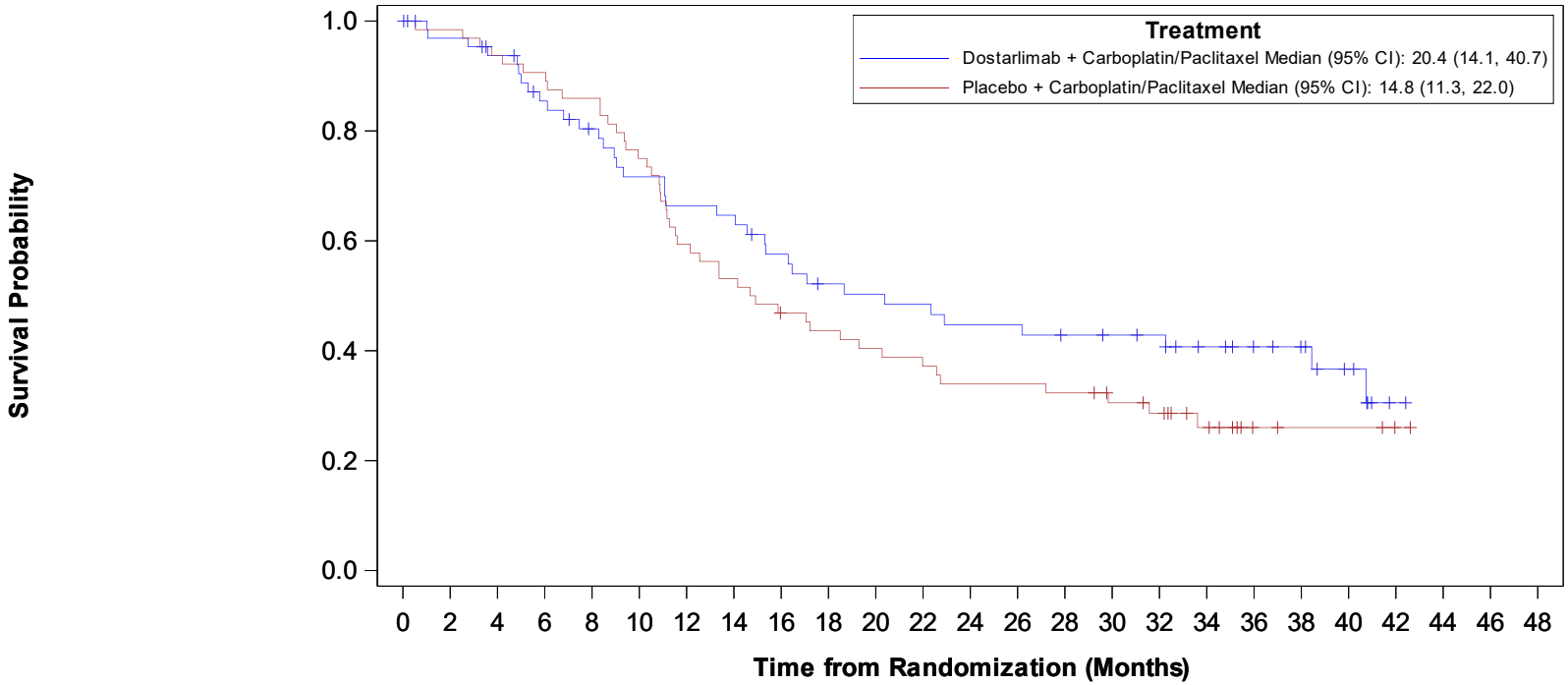
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	35(0)	34(1)	33(1)	33(1)	32(2)	31(3)	28(5)	26(6)	24(8)	23(9)	23(9)	21(11)	20(12)	19(13)	18(14)	18(14)	14(16)	12(16)	8(16)	6(17)	5(17)	3(17)	1(17)	1(17)	0(17)
Placebo + Carboplatin/Paclitaxel (N=184)	33(0)	30(0)	28(2)	26(3)	25(4)	24(5)	22(7)	20(9)	19(10)	19(10)	19(10)	18(11)	17(12)	17(12)	17(12)	17(12)	13(13)	10(13)	7(14)	5(16)	3(16)	3(16)	1(16)	1(16)	0(16)

NE = Not Estimable.
Program: f_2_0702_km_pfs2_dstat.sas, Output: f_2_0702_km_pfs2_dstat.rtf, Generated on: 23JUL2024 19:32,
Data Cutoff Date: 22SEP2023

Figure 2.0702 Graph of Kaplan Meier Curves of Progression Free Survival 2 - RECIST v1.1 based on Investigator Assessment by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage IV



Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=192)	67(0)	62(2)	58(4)	51(9)	46(12)	41(17)	38(20)	37(21)	32(25)	28(28)	27(29)	26(30)	24(32)	24(32)	22(33)	21(33)	20(33)	16(34)	13(34)	11(34)	7(35)	1(36)	0(36)
Placebo + Carboplatin/Paclitaxel (N=184)	64(0)	63(1)	60(4)	58(6)	55(9)	48(16)	38(26)	34(30)	29(34)	27(36)	25(38)	23(40)	21(42)	21(42)	20(43)	17(44)	15(45)	10(46)	4(46)	3(46)	3(46)	1(46)	0(46)

NE = Not Estimable.
Program: f_2_0702_km_pfs2_dstat.sas, Output: f_2_0702_km_pfs2_dstat.rtf, Generated on: 23JUL2024 19:32,
Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	79 (81.4%)	66 (78.6%)
Censored	18 (18.6%)	18 (21.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 1.0)
50%	1.6 (1.4, 2.2)	1.4 (1.0, 2.1)
75%	3.5 (2.6, 11.8)	4.3 (2.8, 19.6)
Survival probability (95% CI) at		
Month 6	20.4% (12.8%, 29.2%)	23.5% (14.8%, 33.5%)
Month 12	15.2% (8.2%, 24.1%)	20.6% (12.3%, 30.4%)
Month 18	15.2% (8.2%, 24.1%)	17.2% (9.5%, 26.8%)
Month 24	15.2% (8.2%, 24.1%)	13.4% (6.5%, 22.8%)
Month 30	15.2% (8.2%, 24.1%)	13.4% (6.5%, 22.8%)
Month 36	NE (NE, NE)	13.4% (6.5%, 22.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.02 (0.727, 1.423)	
p-value of 2-sided stratified log-rank test	0.9417	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	79	66
0	28 (35.4%)	24 (36.4%)
1	12 (15.2%)	10 (15.2%)
2	8 (10.1%)	4 (6.1%)
3	9 (11.4%)	7 (10.6%)
>=4	22 (27.8%)	21 (31.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	80 (84.2%)	81 (81.0%)
Censored	15 (15.8%)	19 (19.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 0.9)
50%	1.4 (0.9, 2.0)	1.5 (1.2, 2.5)
75%	3.0 (2.3, 10.2)	6.8 (2.8, 14.5)
Survival probability (95% CI) at		
Month 6	17.2% (10.1%, 25.9%)	26.6% (18.2%, 35.8%)
Month 12	12.5% (6.4%, 20.9%)	19.3% (11.6%, 28.4%)
Month 18	9.4% (4.1%, 17.4%)	12.8% (6.1%, 22.3%)
Month 24	5.6% (1.7%, 13.2%)	12.8% (6.1%, 22.3%)
Month 30	5.6% (1.7%, 13.2%)	5.1% (1.1%, 14.3%)
Month 36	5.6% (1.7%, 13.2%)	5.1% (1.1%, 14.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.12 (0.816, 1.541)	
p-value of 2-sided stratified log-rank test	0.4493	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	80	81
0	29 (36.3%)	31 (38.3%)
1	12 (15.0%)	14 (17.3%)
2	7 (8.8%)	7 (8.6%)
3	7 (8.8%)	3 (3.7%)
>=4	25 (31.3%)	26 (32.1%)
p-value from Interaction Test[c]	0.6689	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	89 (91.8%)	74 (88.1%)
Censored	8 (8.2%)	10 (11.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 0.9)
50%	1.9 (1.4, 2.2)	1.4 (1.0, 2.1)
75%	3.6 (2.8, 6.5)	4.3 (2.8, 13.3)
Survival probability (95% CI) at		
Month 6	18.6% (11.5%, 26.9%)	22.3% (14.0%, 31.8%)
Month 12	10.8% (5.5%, 18.1%)	19.7% (11.8%, 29.0%)
Month 18	9.6% (4.7%, 16.7%)	14.1% (7.4%, 22.8%)
Month 24	9.6% (4.7%, 16.7%)	9.8% (4.4%, 17.8%)
Month 30	8.4% (3.8%, 15.3%)	8.4% (3.5%, 16.1%)
Month 36	NE (NE, NE)	5.6% (1.5%, 14.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.09 (0.791, 1.502)	
p-value of 2-sided stratified log-rank test	0.6069	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	89	74
0	38 (42.7%)	32 (43.2%)
1	12 (13.5%)	10 (13.5%)
2	8 (9.0%)	4 (5.4%)
3	9 (10.1%)	7 (9.5%)
>=4	22 (24.7%)	21 (28.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	86 (90.5%)	94 (94.0%)
Censored	9 (9.5%)	6 (6.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 0.9)
50%	1.4 (1.0, 2.0)	1.5 (1.2, 2.8)
75%	2.9 (2.2, 8.0)	7.3 (2.8, 12.0)
Survival probability (95% CI) at		
Month 6	16.7% (9.9%, 25.1%)	27.6% (19.1%, 36.6%)
Month 12	11.6% (5.9%, 19.4%)	16.3% (9.8%, 24.3%)
Month 18	7.7% (3.2%, 14.8%)	8.7% (4.2%, 15.5%)
Month 24	3.9% (1.1%, 9.8%)	7.7% (3.4%, 14.1%)
Month 30	3.9% (1.1%, 9.8%)	2.6% (0.5%, 7.8%)
Month 36	3.9% (1.1%, 9.8%)	2.6% (0.5%, 7.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.11 (0.820, 1.497)	
p-value of 2-sided stratified log-rank test	0.4765	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	86	94
0	35 (40.7%)	44 (46.8%)
1	12 (14.0%)	14 (14.9%)
2	7 (8.1%)	7 (7.4%)
3	7 (8.1%)	3 (3.2%)
>=4	25 (29.1%)	26 (27.7%)
p-value from Interaction Test[c]	0.9175	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	61 (62.9%)	53 (63.1%)
Censored	36 (37.1%)	31 (36.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 1.6)	0.9 (0.8, 1.6)
50%	6.1 (2.4, 8.7)	5.8 (2.8, 11.4)
75%	NE (10.4, NE)	40.3 (14.1, NE)
Survival probability (95% CI) at		
Month 6	51.0% (40.5%, 60.6%)	49.6% (38.0%, 60.2%)
Month 12	34.7% (24.6%, 44.9%)	38.1% (26.8%, 49.3%)
Month 18	33.0% (23.0%, 43.4%)	29.1% (18.6%, 40.4%)
Month 24	29.4% (19.6%, 39.9%)	26.9% (16.5%, 38.3%)
Month 30	29.4% (19.6%, 39.9%)	26.9% (16.5%, 38.3%)
Month 36	29.4% (19.6%, 39.9%)	26.9% (16.5%, 38.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.03 (0.708, 1.496)	
p-value of 2-sided stratified log-rank test	0.8686	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	61	53
0	34 (55.7%)	29 (54.7%)
1	10 (16.4%)	4 (7.5%)
2	3 (4.9%)	10 (18.9%)
3	4 (6.6%)	2 (3.8%)
>=4	10 (16.4%)	8 (15.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	57 (60.0%)	64 (64.0%)
Censored	38 (40.0%)	36 (36.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 2.1)	1.0 (0.8, 1.6)
50%	4.1 (2.8, 8.5)	5.2 (2.1, 9.7)
75%	NE (12.6, NE)	NE (10.9, NE)
Survival probability (95% CI) at		
Month 6	47.2% (36.1%, 57.4%)	43.8% (33.5%, 53.6%)
Month 12	36.8% (26.2%, 47.5%)	32.9% (23.2%, 43.0%)
Month 18	33.0% (22.4%, 43.9%)	30.1% (20.6%, 40.2%)
Month 24	25.9% (15.6%, 37.4%)	30.1% (20.6%, 40.2%)
Month 30	25.9% (15.6%, 37.4%)	27.6% (17.9%, 38.1%)
Month 36	25.9% (15.6%, 37.4%)	27.6% (17.9%, 38.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.92 (0.637, 1.315)	
p-value of 2-sided stratified log-rank test	0.6464	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	57	64
0	31 (54.4%)	20 (31.3%)
1	13 (22.8%)	19 (29.7%)
2	3 (5.3%)	8 (12.5%)
3	1 (1.8%)	3 (4.7%)
>=4	9 (15.8%)	14 (21.9%)
p-value from Interaction Test[c]	0.7124	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	67 (69.1%)	55 (65.5%)
Censored	30 (30.9%)	29 (34.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.4)	0.8 (0.7, 1.4)
50%	2.8 (1.6, 5.2)	2.9 (2.1, 8.7)
75%	42.5 (17.0, NE)	32.3 (11.1, NE)
Survival probability (95% CI) at		
Month 6	38.0% (28.2%, 47.8%)	43.1% (32.0%, 53.7%)
Month 12	36.8% (27.0%, 46.5%)	33.5% (22.9%, 44.4%)
Month 18	33.7% (24.1%, 43.6%)	31.5% (21.1%, 42.6%)
Month 24	32.2% (22.6%, 42.2%)	29.1% (18.7%, 40.4%)
Month 30	27.2% (18.0%, 37.4%)	26.7% (16.3%, 38.2%)
Month 36	25.3% (16.1%, 35.5%)	24.0% (13.9%, 35.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.95 (0.662, 1.364)	
p-value of 2-sided stratified log-rank test	0.7852	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	67	55
0	43 (64.2%)	33 (60.0%)
1	13 (19.4%)	11 (20.0%)
2	5 (7.5%)	4 (7.3%)
3	4 (6.0%)	2 (3.6%)
>=4	2 (3.0%)	5 (9.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	61 (64.2%)	57 (57.0%)
Censored	34 (35.8%)	43 (43.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.0)	1.7 (1.0, 3.9)
50%	3.5 (2.8, 4.7)	11.6 (4.3, 16.8)
75%	37.7 (9.9, NE)	NE (19.7, NE)
Survival probability (95% CI) at		
Month 6	39.4% (29.0%, 49.6%)	55.4% (44.8%, 64.8%)
Month 12	35.0% (24.9%, 45.3%)	49.8% (38.9%, 59.7%)
Month 18	33.3% (23.2%, 43.7%)	37.7% (26.7%, 48.7%)
Month 24	26.8% (16.9%, 37.8%)	35.6% (24.6%, 46.8%)
Month 30	26.8% (16.9%, 37.8%)	33.3% (22.2%, 44.7%)
Month 36	26.8% (16.9%, 37.8%)	26.1% (14.5%, 39.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.30 (0.899, 1.884)	
p-value of 2-sided stratified log-rank test	0.1638	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	61	57
0	42 (68.9%)	45 (78.9%)
1	6 (9.8%)	6 (10.5%)
2	7 (11.5%)	3 (5.3%)
3	3 (4.9%)	3 (5.3%)
>=4	3 (4.9%)	0
p-value from Interaction Test[c]	0.1752	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	79 (81.4%)	69 (82.1%)
Censored	18 (18.6%)	15 (17.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.1 (0.8, 1.5)	0.8 (0.7, 1.4)
50%	2.8 (1.6, 4.9)	2.9 (2.1, 7.9)
75%	23.8 (6.9, 34.0)	16.3 (11.1, 24.6)
Survival probability (95% CI) at		
Month 6	37.0% (27.4%, 46.6%)	42.1% (31.3%, 52.5%)
Month 12	30.5% (21.5%, 39.9%)	32.9% (22.9%, 43.3%)
Month 18	27.0% (18.4%, 36.3%)	22.4% (13.9%, 32.1%)
Month 24	24.6% (16.4%, 33.8%)	16.9% (9.5%, 26.1%)
Month 30	18.8% (11.5%, 27.4%)	14.1% (7.4%, 22.9%)
Month 36	15.5% (8.6%, 24.2%)	12.7% (6.4%, 21.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.92 (0.666, 1.281)	
p-value of 2-sided stratified log-rank test	0.6412	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	79	69
0	55 (69.6%)	47 (68.1%)
1	13 (16.5%)	11 (15.9%)
2	5 (6.3%)	4 (5.8%)
3	4 (5.1%)	2 (2.9%)
>=4	2 (2.5%)	5 (7.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	78 (82.1%)	83 (83.0%)
Censored	17 (17.9%)	17 (17.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.1 (0.8, 1.7)	1.7 (1.0, 3.9)
50%	3.4 (2.2, 4.6)	8.8 (4.4, 12.0)
75%	19.2 (8.3, 24.6)	18.4 (13.4, 30.4)
Survival probability (95% CI) at		
Month 6	38.1% (28.1%, 48.0%)	56.1% (45.7%, 65.3%)
Month 12	32.0% (22.5%, 41.8%)	39.6% (29.9%, 49.1%)
Month 18	28.1% (19.1%, 37.8%)	26.0% (17.8%, 35.0%)
Month 24	18.8% (11.2%, 28.0%)	18.5% (11.4%, 26.8%)
Month 30	14.5% (7.8%, 23.2%)	17.2% (10.4%, 25.5%)
Month 36	13.0% (6.7%, 21.6%)	11.9% (5.8%, 20.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.16 (0.843, 1.603)	
p-value of 2-sided stratified log-rank test	0.3635	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	78	83
0	59 (75.6%)	71 (85.5%)
1	6 (7.7%)	6 (7.2%)
2	7 (9.0%)	3 (3.6%)
3	3 (3.8%)	3 (3.6%)
>=4	3 (3.8%)	0
p-value from Interaction Test[c]	0.2198	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	28 (28.9%)	24 (28.6%)
Censored	69 (71.1%)	60 (71.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.5 (2.1, NE)	2.0 (0.9, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	71.1% (60.7%, 79.2%)	70.5% (59.0%, 79.4%)
Month 12	71.1% (60.7%, 79.2%)	69.0% (57.3%, 78.1%)
Month 18	71.1% (60.7%, 79.2%)	69.0% (57.3%, 78.1%)
Month 24	71.1% (60.7%, 79.2%)	69.0% (57.3%, 78.1%)
Month 30	71.1% (60.7%, 79.2%)	69.0% (57.3%, 78.1%)
Month 36	66.0% (51.5%, 77.1%)	69.0% (57.3%, 78.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.06 (0.609, 1.838)	
p-value of 2-sided stratified log-rank test	0.8505	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	28	24
0	12 (42.9%)	5 (20.8%)
1	5 (17.9%)	4 (16.7%)
2	2 (7.1%)	5 (20.8%)
3	3 (10.7%)	3 (12.5%)
>=4	6 (21.4%)	7 (29.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	19 (20.0%)	19 (19.0%)
Censored	76 (80.0%)	81 (81.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (1.6, NE)	NE (1.4, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	79.2% (69.0%, 86.4%)	81.4% (72.1%, 87.8%)
Month 12	77.7% (67.2%, 85.2%)	79.7% (69.9%, 86.6%)
Month 18	77.7% (67.2%, 85.2%)	79.7% (69.9%, 86.6%)
Month 24	77.7% (67.2%, 85.2%)	79.7% (69.9%, 86.6%)
Month 30	77.7% (67.2%, 85.2%)	79.7% (69.9%, 86.6%)
Month 36	77.7% (67.2%, 85.2%)	79.7% (69.9%, 86.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.83 (0.433, 1.593)	
p-value of 2-sided stratified log-rank test	0.5718	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	19	19
0	5 (26.3%)	8 (42.1%)
1	2 (10.5%)	0
2	2 (10.5%)	1 (5.3%)
3	1 (5.3%)	2 (10.5%)
>=4	9 (47.4%)	8 (42.1%)
p-value from Interaction Test[c]	0.7015	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	68 (70.1%)	57 (67.9%)
Censored	29 (29.9%)	27 (32.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (1.0, 2.8)	1.0 (0.8, 1.4)
50%	5.5 (3.5, 9.9)	3.5 (2.1, 5.6)
75%	19.8 (11.7, NE)	20.7 (7.0, NE)
Survival probability (95% CI) at		
Month 6	49.2% (38.6%, 59.0%)	38.2% (27.4%, 49.0%)
Month 12	34.2% (24.1%, 44.4%)	27.2% (17.4%, 37.9%)
Month 18	28.3% (18.8%, 38.5%)	25.1% (15.4%, 35.9%)
Month 24	21.6% (13.0%, 31.7%)	21.9% (12.3%, 33.4%)
Month 30	21.6% (13.0%, 31.7%)	21.9% (12.3%, 33.4%)
Month 36	15.4% (6.9%, 26.9%)	21.9% (12.3%, 33.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.79 (0.549, 1.128)	
p-value of 2-sided stratified log-rank test	0.1955	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	68	57
0	37 (54.4%)	23 (40.4%)
1	7 (10.3%)	16 (28.1%)
2	13 (19.1%)	7 (12.3%)
3	1 (1.5%)	1 (1.8%)
>=4	10 (14.7%)	10 (17.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	67 (70.5%)	70 (70.0%)
Censored	28 (29.5%)	30 (30.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.7 (0.8, 2.8)
50%	2.4 (1.5, 4.6)	5.6 (3.4, 7.2)
75%	15.3 (5.8, 34.4)	18.1 (8.8, 33.9)
Survival probability (95% CI) at		
Month 6	34.7% (24.7%, 44.9%)	48.0% (37.6%, 57.7%)
Month 12	28.5% (18.9%, 38.8%)	31.8% (22.1%, 42.0%)
Month 18	22.5% (13.3%, 33.1%)	25.1% (15.9%, 35.4%)
Month 24	17.1% (8.5%, 28.2%)	16.6% (8.5%, 27.1%)
Month 30	17.1% (8.5%, 28.2%)	16.6% (8.5%, 27.1%)
Month 36	8.6% (2.0%, 21.4%)	12.5% (4.7%, 24.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.10 (0.781, 1.552)	
p-value of 2-sided stratified log-rank test	0.5774	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	67	70
0	40 (59.7%)	40 (57.1%)
1	4 (6.0%)	12 (17.1%)
2	10 (14.9%)	6 (8.6%)
3	4 (6.0%)	2 (2.9%)
>=4	9 (13.4%)	10 (14.3%)
p-value from Interaction Test[c]	0.2176	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	83 (85.6%)	73 (86.9%)
Censored	14 (14.4%)	11 (13.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (1.0, 2.8)	0.9 (0.8, 1.4)
50%	5.0 (3.5, 7.6)	3.5 (2.1, 5.4)
75%	13.2 (9.8, 20.7)	12.6 (6.5, 19.0)
Survival probability (95% CI) at		
Month 6	46.3% (36.0%, 55.9%)	35.4% (25.2%, 45.6%)
Month 12	28.7% (19.9%, 38.1%)	25.1% (16.2%, 34.9%)
Month 18	20.9% (13.3%, 29.7%)	18.1% (10.5%, 27.4%)
Month 24	15.1% (8.6%, 23.3%)	11.1% (5.3%, 19.4%)
Month 30	12.8% (6.9%, 20.6%)	8.4% (3.5%, 16.0%)
Month 36	9.1% (3.9%, 17.1%)	8.4% (3.5%, 16.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.78 (0.562, 1.072)	
p-value of 2-sided stratified log-rank test	0.1261	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	83	73
0	52 (62.7%)	39 (53.4%)
1	7 (8.4%)	16 (21.9%)
2	13 (15.7%)	7 (9.6%)
3	1 (1.2%)	1 (1.4%)
>=4	10 (12.0%)	10 (13.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	82 (86.3%)	90 (90.0%)
Censored	13 (13.7%)	10 (10.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.7 (0.8, 2.8)
50%	2.3 (1.4, 4.3)	5.1 (3.4, 7.3)
75%	12.9 (5.8, 19.2)	12.9 (8.8, 17.8)
Survival probability (95% CI) at		
Month 6	34.5% (24.8%, 44.4%)	48.0% (37.8%, 57.4%)
Month 12	26.9% (18.0%, 36.6%)	28.2% (19.6%, 37.3%)
Month 18	19.2% (11.6%, 28.3%)	16.7% (10.1%, 24.8%)
Month 24	10.2% (4.8%, 18.0%)	9.1% (4.4%, 16.0%)
Month 30	9.0% (4.0%, 16.4%)	9.1% (4.4%, 16.0%)
Month 36	3.7% (0.8%, 10.6%)	5.5% (1.8%, 12.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.08 (0.794, 1.464)	
p-value of 2-sided stratified log-rank test	0.6245	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	82	90
0	55 (67.1%)	60 (66.7%)
1	4 (4.9%)	12 (13.3%)
2	10 (12.2%)	6 (6.7%)
3	4 (4.9%)	2 (2.2%)
>=4	9 (11.0%)	10 (11.1%)
p-value from Interaction Test[c]	0.1689	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	64 (66.0%)	42 (50.0%)
Censored	33 (34.0%)	42 (50.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 1.4)
50%	2.1 (1.2, 3.5)	10.2 (1.5, NE)
75%	NE (9.7, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	37.3% (27.5%, 47.0%)	50.6% (39.0%, 61.0%)
Month 12	34.3% (24.6%, 44.1%)	48.9% (37.3%, 59.5%)
Month 18	31.0% (21.5%, 41.0%)	44.9% (33.1%, 56.0%)
Month 24	31.0% (21.5%, 41.0%)	44.9% (33.1%, 56.0%)
Month 30	31.0% (21.5%, 41.0%)	44.9% (33.1%, 56.0%)
Month 36	28.6% (18.9%, 39.0%)	44.9% (33.1%, 56.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.68 (0.458, 1.010)	
p-value of 2-sided stratified log-rank test	0.0460	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	64	42
0	31 (48.4%)	17 (40.5%)
1	6 (9.4%)	5 (11.9%)
2	6 (9.4%)	6 (14.3%)
3	3 (4.7%)	3 (7.1%)
>=4	18 (28.1%)	11 (26.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	58 (61.1%)	52 (52.0%)
Censored	37 (38.9%)	48 (48.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.4)	0.8 (0.8, 1.4)
50%	2.1 (1.4, 4.8)	5.2 (1.4, NE)
75%	NE (11.4, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	38.9% (28.6%, 49.1%)	49.1% (38.8%, 58.6%)
Month 12	34.7% (24.6%, 44.9%)	46.6% (36.2%, 56.2%)
Month 18	32.9% (22.9%, 43.3%)	45.0% (34.5%, 54.8%)
Month 24	31.0% (21.0%, 41.5%)	45.0% (34.5%, 54.8%)
Month 30	31.0% (21.0%, 41.5%)	45.0% (34.5%, 54.8%)
Month 36	31.0% (21.0%, 41.5%)	45.0% (34.5%, 54.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.71 (0.485, 1.045)	
p-value of 2-sided stratified log-rank test	0.0845	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	58	52
0	27 (46.6%)	17 (32.7%)
1	11 (19.0%)	13 (25.0%)
2	8 (13.8%)	4 (7.7%)
3	1 (1.7%)	1 (1.9%)
>=4	11 (19.0%)	17 (32.7%)
p-value from Interaction Test[c]	0.8416	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	60 (61.9%)	55 (65.5%)
Censored	37 (38.1%)	29 (34.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.2)	1.4 (1.0, 2.1)
50%	4.3 (3.4, 14.7)	3.6 (2.8, 9.2)
75%	NE (25.3, NE)	28.6 (15.2, NE)
Survival probability (95% CI) at		
Month 6	48.5% (38.0%, 58.2%)	44.5% (33.1%, 55.2%)
Month 12	43.0% (32.5%, 53.1%)	36.7% (25.8%, 47.7%)
Month 18	36.1% (25.6%, 46.7%)	32.8% (22.0%, 44.0%)
Month 24	36.1% (25.6%, 46.7%)	28.7% (18.2%, 40.0%)
Month 30	26.7% (16.3%, 38.3%)	22.9% (12.7%, 35.0%)
Month 36	26.7% (16.3%, 38.3%)	11.5% (1.4%, 33.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.90 (0.622, 1.313)	
p-value of 2-sided stratified log-rank test	0.5610	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	60	55
0	30 (50.0%)	25 (45.5%)
1	10 (16.7%)	11 (20.0%)
2	7 (11.7%)	4 (7.3%)
3	2 (3.3%)	7 (12.7%)
>=4	11 (18.3%)	8 (14.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	60 (63.2%)	66 (66.0%)
Censored	35 (36.8%)	34 (34.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.2)	1.6 (1.1, 2.5)
50%	3.0 (2.3, 8.9)	4.1 (2.8, 8.5)
75%	30.2 (15.4, NE)	24.7 (10.0, NE)
Survival probability (95% CI) at		
Month 6	42.7% (32.2%, 52.8%)	44.8% (34.5%, 54.5%)
Month 12	38.4% (28.0%, 48.6%)	30.2% (20.5%, 40.4%)
Month 18	34.8% (24.4%, 45.3%)	28.5% (19.0%, 38.8%)
Month 24	29.9% (19.5%, 41.1%)	26.1% (16.6%, 36.7%)
Month 30	26.6% (15.9%, 38.6%)	19.9% (10.4%, 31.7%)
Month 36	19.4% (9.1%, 32.6%)	19.9% (10.4%, 31.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.96 (0.670, 1.379)	
p-value of 2-sided stratified log-rank test	0.7957	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	60	66
0	35 (58.3%)	35 (53.0%)
1	7 (11.7%)	12 (18.2%)
2	4 (6.7%)	3 (4.5%)
3	4 (6.7%)	5 (7.6%)
>=4	10 (16.7%)	11 (16.7%)
p-value from Interaction Test[c]	0.7577	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	80 (82.5%)	68 (81.0%)
Censored	17 (17.5%)	16 (19.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 2.6)	1.4 (0.8, 2.1)
50%	4.3 (3.4, 8.4)	3.8 (2.8, 9.2)
75%	19.5 (12.1, 29.0)	16.8 (11.0, 28.2)
Survival probability (95% CI) at		
Month 6	46.4% (36.1%, 56.0%)	43.9% (32.9%, 54.4%)
Month 12	35.3% (25.7%, 44.9%)	34.4% (24.1%, 45.0%)
Month 18	27.0% (18.4%, 36.5%)	24.8% (15.8%, 34.9%)
Month 24	23.5% (15.3%, 32.7%)	17.8% (10.1%, 27.3%)
Month 30	15.3% (8.7%, 23.6%)	12.9% (6.4%, 21.9%)
Month 36	11.8% (5.8%, 20.1%)	6.5% (0.9%, 20.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.95 (0.683, 1.324)	
p-value of 2-sided stratified log-rank test	0.7358	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	80	68
0	50 (62.5%)	38 (55.9%)
1	10 (12.5%)	11 (16.2%)
2	7 (8.8%)	4 (5.9%)
3	2 (2.5%)	7 (10.3%)
>=4	11 (13.8%)	8 (11.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	76 (80.0%)	86 (86.0%)
Censored	19 (20.0%)	14 (14.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (1.0, 2.1)	1.6 (1.1, 2.5)
50%	2.9 (2.2, 5.9)	4.2 (2.9, 8.2)
75%	18.9 (8.9, 28.0)	12.2 (8.8, 22.7)
Survival probability (95% CI) at		
Month 6	40.0% (29.9%, 50.0%)	44.8% (34.7%, 54.3%)
Month 12	34.0% (24.3%, 43.9%)	25.6% (17.3%, 34.6%)
Month 18	26.4% (17.5%, 36.1%)	21.2% (13.6%, 29.9%)
Month 24	20.6% (12.5%, 30.0%)	15.0% (8.6%, 23.2%)
Month 30	14.2% (7.4%, 23.2%)	9.4% (4.2%, 17.0%)
Month 36	9.2% (3.8%, 17.6%)	9.4% (4.2%, 17.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.98 (0.714, 1.351)	
p-value of 2-sided stratified log-rank test	0.8826	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	76	86
0	51 (67.1%)	55 (64.0%)
1	7 (9.2%)	12 (14.0%)
2	4 (5.3%)	3 (3.5%)
3	4 (5.3%)	5 (5.8%)
>=4	10 (13.2%)	11 (12.8%)
p-value from Interaction Test[c]	0.7833	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	27 (27.8%)	13 (15.5%)
Censored	70 (72.2%)	71 (84.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	13.7 (2.1, NE)	NE (4.4, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	77.5% (67.6%, 84.7%)	84.5% (74.3%, 90.9%)
Month 12	76.1% (65.9%, 83.6%)	84.5% (74.3%, 90.9%)
Month 18	73.0% (62.2%, 81.1%)	82.7% (72.0%, 89.6%)
Month 24	69.3% (57.8%, 78.3%)	82.7% (72.0%, 89.6%)
Month 30	69.3% (57.8%, 78.3%)	82.7% (72.0%, 89.6%)
Month 36	66.9% (54.8%, 76.5%)	82.7% (72.0%, 89.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.58 (0.296, 1.119)	
p-value of 2-sided stratified log-rank test	0.1002	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	27	13
0	11 (40.7%)	6 (46.2%)
1	4 (14.8%)	2 (15.4%)
2	5 (18.5%)	0
3	2 (7.4%)	2 (15.4%)
>=4	5 (18.5%)	3 (23.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	27 (28.4%)	25 (25.0%)
Censored	68 (71.6%)	75 (75.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	4.8 (1.4, NE)	13.9 (2.1, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	73.1% (62.3%, 81.3%)	80.1% (70.5%, 86.8%)
Month 12	68.5% (57.0%, 77.4%)	75.8% (65.5%, 83.5%)
Month 18	66.6% (54.9%, 76.0%)	74.1% (63.3%, 82.2%)
Month 24	66.6% (54.9%, 76.0%)	69.8% (57.9%, 79.0%)
Month 30	66.6% (54.9%, 76.0%)	69.8% (57.9%, 79.0%)
Month 36	66.6% (54.9%, 76.0%)	69.8% (57.9%, 79.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.73 (0.418, 1.264)	
p-value of 2-sided stratified log-rank test	0.2593	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	27	25
0	18 (66.7%)	8 (32.0%)
1	1 (3.7%)	7 (28.0%)
2	3 (11.1%)	2 (8.0%)
3	0	1 (4.0%)
>=4	5 (18.5%)	7 (28.0%)
p-value from Interaction Test[c]	0.4763	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	48 (49.5%)	42 (50.0%)
Censored	49 (50.5%)	42 (50.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.4, 4.3)	1.5 (0.9, 2.4)
50%	14.3 (7.7, NE)	6.4 (3.6, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	60.9% (50.1%, 70.1%)	50.4% (38.6%, 61.0%)
Month 12	50.5% (39.2%, 60.8%)	48.9% (37.2%, 59.6%)
Month 18	47.1% (35.6%, 57.7%)	43.0% (31.2%, 54.4%)
Month 24	47.1% (35.6%, 57.7%)	43.0% (31.2%, 54.4%)
Month 30	40.4% (28.5%, 51.9%)	43.0% (31.2%, 54.4%)
Month 36	40.4% (28.5%, 51.9%)	43.0% (31.2%, 54.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.82 (0.539, 1.253)	
p-value of 2-sided stratified log-rank test	0.3628	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	48	42
0	36 (75.0%)	32 (76.2%)
1	6 (12.5%)	5 (11.9%)
2	1 (2.1%)	0
3	2 (4.2%)	0
>=4	3 (6.3%)	5 (11.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	52 (54.7%)	54 (54.0%)
Censored	43 (45.3%)	46 (46.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (0.9, 2.2)	1.5 (0.8, 2.3)
50%	5.5 (2.6, 19.4)	9.1 (3.0, 29.3)
75%	41.7 (41.7, NE)	NE (29.3, NE)
Survival probability (95% CI) at		
Month 6	46.3% (35.4%, 56.5%)	51.3% (40.8%, 60.9%)
Month 12	41.9% (31.1%, 52.4%)	43.9% (33.2%, 54.1%)
Month 18	40.2% (29.4%, 50.7%)	42.1% (31.3%, 52.5%)
Month 24	38.1% (27.2%, 48.9%)	39.9% (28.9%, 50.6%)
Month 30	38.1% (27.2%, 48.9%)	36.6% (24.9%, 48.2%)
Month 36	38.1% (27.2%, 48.9%)	36.6% (24.9%, 48.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.03 (0.704, 1.518)	
p-value of 2-sided stratified log-rank test	0.8568	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	52	54
0	25 (48.1%)	29 (53.7%)
1	12 (23.1%)	11 (20.4%)
2	8 (15.4%)	7 (13.0%)
3	1 (1.9%)	2 (3.7%)
>=4	6 (11.5%)	5 (9.3%)
p-value from Interaction Test[c]	0.4314	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	70 (72.2%)	61 (72.6%)
Censored	27 (27.8%)	23 (27.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.4, 3.6)	1.5 (0.9, 2.3)
50%	8.3 (5.3, 13.2)	4.4 (3.5, 12.7)
75%	29.7 (22.4, NE)	21.9 (13.3, NE)
Survival probability (95% CI) at		
Month 6	57.7% (47.0%, 66.9%)	45.7% (34.7%, 56.1%)
Month 12	41.3% (31.1%, 51.3%)	41.7% (30.8%, 52.2%)
Month 18	35.2% (25.4%, 45.1%)	30.2% (20.3%, 40.7%)
Month 24	33.9% (24.2%, 43.8%)	24.2% (15.1%, 34.5%)
Month 30	23.5% (15.0%, 33.0%)	21.2% (12.6%, 31.2%)
Month 36	20.1% (12.0%, 29.6%)	21.2% (12.6%, 31.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.86 (0.605, 1.218)	
p-value of 2-sided stratified log-rank test	0.3968	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	70	61
0	58 (82.9%)	51 (83.6%)
1	6 (8.6%)	5 (8.2%)
2	1 (1.4%)	0
3	2 (2.9%)	0
>=4	3 (4.3%)	5 (8.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	72 (75.8%)	88 (88.0%)
Censored	23 (24.2%)	12 (12.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.9, 2.1)	1.5 (0.8, 2.3)
50%	3.1 (2.5, 11.3)	6.4 (3.0, 10.3)
75%	21.1 (17.4, NE)	18.5 (12.5, 27.0)
Survival probability (95% CI) at		
Month 6	44.7% (34.3%, 54.7%)	51.0% (40.7%, 60.4%)
Month 12	39.9% (29.7%, 49.9%)	35.4% (26.1%, 44.9%)
Month 18	33.7% (23.9%, 43.6%)	25.8% (17.5%, 34.8%)
Month 24	24.7% (16.0%, 34.3%)	20.3% (12.9%, 28.9%)
Month 30	21.9% (13.7%, 31.4%)	14.3% (8.1%, 22.4%)
Month 36	19.2% (11.4%, 28.5%)	10.8% (5.1%, 18.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

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Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.84 (0.614, 1.157)	
p-value of 2-sided stratified log-rank test	0.3009	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	72	88
0	45 (62.5%)	63 (71.6%)
1	12 (16.7%)	11 (12.5%)
2	8 (11.1%)	7 (8.0%)
3	1 (1.4%)	2 (2.3%)
>=4	6 (8.3%)	5 (5.7%)
p-value from Interaction Test[c]	0.9077	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	62 (63.9%)	47 (56.0%)
Censored	35 (36.1%)	37 (44.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	0.9 (0.7, 1.4)
50%	2.3 (1.7, 7.1)	4.5 (1.6, 25.8)
75%	NE (28.3, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	41.8% (31.8%, 51.5%)	47.2% (35.7%, 57.9%)
Month 12	35.6% (25.9%, 45.4%)	39.2% (27.9%, 50.3%)
Month 18	35.6% (25.9%, 45.4%)	39.2% (27.9%, 50.3%)
Month 24	35.6% (25.9%, 45.4%)	39.2% (27.9%, 50.3%)
Month 30	33.5% (23.7%, 43.6%)	36.7% (25.3%, 48.2%)
Month 36	30.2% (19.7%, 41.3%)	36.7% (25.3%, 48.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.90 (0.612, 1.317)	
p-value of 2-sided stratified log-rank test	0.5595	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	62	47
0	24 (38.7%)	22 (46.8%)
1	14 (22.6%)	5 (10.6%)
2	5 (8.1%)	7 (14.9%)
3	4 (6.5%)	3 (6.4%)
>=4	15 (24.2%)	10 (21.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	42 (44.2%)	52 (52.0%)
Censored	53 (55.8%)	48 (48.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.1 (0.8, 2.7)	1.0 (0.8, 1.6)
50%	NE (3.0, NE)	6.9 (4.2, NE)
75%	NE (NE, NE)	NE (31.8, NE)
Survival probability (95% CI) at		
Month 6	53.3% (42.1%, 63.3%)	54.2% (43.5%, 63.8%)
Month 12	50.1% (38.8%, 60.4%)	44.7% (33.9%, 54.9%)
Month 18	50.1% (38.8%, 60.4%)	42.8% (31.9%, 53.2%)
Month 24	50.1% (38.8%, 60.4%)	42.8% (31.9%, 53.2%)
Month 30	50.1% (38.8%, 60.4%)	42.8% (31.9%, 53.2%)
Month 36	50.1% (38.8%, 60.4%)	37.5% (24.1%, 50.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.18 (0.775, 1.785)	
p-value of 2-sided stratified log-rank test	0.4353	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	42	52
0	14 (33.3%)	19 (36.5%)
1	6 (14.3%)	9 (17.3%)
2	4 (9.5%)	6 (11.5%)
3	2 (4.8%)	4 (7.7%)
>=4	16 (38.1%)	14 (26.9%)
p-value from Interaction Test[c]	0.3178	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	56 (57.7%)	47 (56.0%)
Censored	41 (42.3%)	37 (44.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.3 (1.4, 3.8)	1.4 (0.8, 2.1)
50%	8.2 (4.4, 21.3)	6.6 (2.8, 27.4)
75%	NE (23.8, NE)	NE (32.2, NE)
Survival probability (95% CI) at		
Month 6	56.9% (46.2%, 66.3%)	52.4% (40.7%, 62.9%)
Month 12	45.1% (34.3%, 55.2%)	43.0% (31.5%, 54.0%)
Month 18	43.6% (32.8%, 53.8%)	39.6% (28.1%, 50.8%)
Month 24	34.8% (24.2%, 45.7%)	39.6% (28.1%, 50.8%)
Month 30	33.0% (22.4%, 43.9%)	37.1% (25.5%, 48.6%)
Month 36	33.0% (22.4%, 43.9%)	33.7% (21.8%, 46.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.86 (0.584, 1.276)	
p-value of 2-sided stratified log-rank test	0.4667	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	56	47
0	34 (60.7%)	31 (66.0%)
1	14 (25.0%)	7 (14.9%)
2	4 (7.1%)	4 (8.5%)
3	3 (5.4%)	2 (4.3%)
>=4	1 (1.8%)	3 (6.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	58 (61.1%)	68 (68.0%)
Censored	37 (38.9%)	32 (32.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 1.5)	2.1 (1.2, 3.0)
50%	5.6 (2.2, 13.4)	8.3 (3.5, 12.5)
75%	37.5 (15.4, NE)	28.4 (16.7, NE)
Survival probability (95% CI) at		
Month 6	47.9% (36.9%, 58.0%)	53.3% (42.7%, 62.8%)
Month 12	40.3% (29.5%, 50.9%)	40.0% (29.6%, 50.2%)
Month 18	35.4% (24.8%, 46.2%)	31.4% (21.6%, 41.7%)
Month 24	27.4% (17.2%, 38.6%)	29.8% (20.1%, 40.1%)
Month 30	27.4% (17.2%, 38.6%)	22.5% (13.5%, 32.9%)
Month 36	27.4% (17.2%, 38.6%)	17.5% (9.0%, 28.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.06 (0.740, 1.527)	
p-value of 2-sided stratified log-rank test	0.7435	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	58	68
0	33 (56.9%)	36 (52.9%)
1	7 (12.1%)	12 (17.6%)
2	6 (10.3%)	6 (8.8%)
3	5 (8.6%)	5 (7.4%)
>=4	7 (12.1%)	9 (13.2%)
p-value from Interaction Test[c]	0.4202	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	75 (77.3%)	64 (76.2%)
Censored	22 (22.7%)	20 (23.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.3 (1.4, 3.8)	1.4 (0.8, 2.1)
50%	6.9 (4.4, 9.5)	4.2 (2.8, 11.0)
75%	26.3 (18.7, NE)	21.9 (14.3, NE)
Survival probability (95% CI) at		
Month 6	54.8% (44.2%, 64.1%)	47.0% (35.8%, 57.3%)
Month 12	36.1% (26.5%, 45.8%)	38.1% (27.6%, 48.6%)
Month 18	35.0% (25.4%, 44.6%)	29.2% (19.7%, 39.4%)
Month 24	27.7% (18.9%, 37.2%)	23.8% (15.1%, 33.7%)
Month 30	21.7% (13.8%, 30.8%)	20.9% (12.7%, 30.6%)
Month 36	16.3% (9.0%, 25.5%)	19.0% (11.0%, 28.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.83 (0.591, 1.163)	
p-value of 2-sided stratified log-rank test	0.2774	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	75	64
0	53 (70.7%)	48 (75.0%)
1	14 (18.7%)	7 (10.9%)
2	4 (5.3%)	4 (6.3%)
3	3 (4.0%)	2 (3.1%)
>=4	1 (1.3%)	3 (4.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	72 (75.8%)	88 (88.0%)
Censored	23 (24.2%)	12 (12.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	2.1 (1.2, 3.0)
50%	4.2 (2.2, 9.7)	8.2 (4.1, 10.3)
75%	20.5 (13.4, 37.5)	17.7 (12.2, 28.4)
Survival probability (95% CI) at		
Month 6	45.9% (35.4%, 55.8%)	53.1% (42.7%, 62.4%)
Month 12	36.0% (26.1%, 46.0%)	34.4% (25.1%, 43.8%)
Month 18	29.6% (20.3%, 39.5%)	25.0% (16.9%, 33.9%)
Month 24	20.2% (12.2%, 29.5%)	21.7% (14.1%, 30.4%)
Month 30	18.8% (11.1%, 28.1%)	14.9% (8.5%, 22.9%)
Month 36	17.4% (10.0%, 26.5%)	9.5% (4.4%, 16.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.05 (0.761, 1.449)	
p-value of 2-sided stratified log-rank test	0.7673	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	72	88
0	47 (65.3%)	56 (63.6%)
1	7 (9.7%)	12 (13.6%)
2	6 (8.3%)	6 (6.8%)
3	5 (6.9%)	5 (5.7%)
>=4	7 (9.7%)	9 (10.2%)
p-value from Interaction Test[c]	0.3629	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	41 (42.3%)	29 (34.5%)
Censored	56 (57.7%)	55 (65.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 1.8)	2.1 (0.9, 13.0)
50%	NE (7.2, NE)	NE (27.4, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	60.8% (50.2%, 69.9%)	69.1% (57.5%, 78.2%)
Month 12	56.8% (46.0%, 66.3%)	66.1% (54.3%, 75.6%)
Month 18	56.8% (46.0%, 66.3%)	62.4% (50.2%, 72.5%)
Month 24	54.9% (43.8%, 64.7%)	62.4% (50.2%, 72.5%)
Month 30	54.9% (43.8%, 64.7%)	60.1% (47.4%, 70.7%)
Month 36	54.9% (43.8%, 64.7%)	60.1% (47.4%, 70.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.76 (0.471, 1.239)	
p-value of 2-sided stratified log-rank test	0.2754	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	41	29
0	14 (34.1%)	15 (51.7%)
1	5 (12.2%)	2 (6.9%)
2	5 (12.2%)	5 (17.2%)
3	4 (9.8%)	1 (3.4%)
>=4	13 (31.7%)	6 (20.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	29 (30.5%)	32 (32.0%)
Censored	66 (69.5%)	68 (68.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.4, 19.9)	1.6 (0.8, 13.9)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	69.5% (58.5%, 78.1%)	68.9% (58.6%, 77.1%)
Month 12	66.7% (55.4%, 75.7%)	68.9% (58.6%, 77.1%)
Month 18	66.7% (55.4%, 75.7%)	65.3% (54.3%, 74.3%)
Month 24	64.4% (52.5%, 74.0%)	65.3% (54.3%, 74.3%)
Month 30	64.4% (52.5%, 74.0%)	65.3% (54.3%, 74.3%)
Month 36	64.4% (52.5%, 74.0%)	65.3% (54.3%, 74.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.02 (0.610, 1.692)	
p-value of 2-sided stratified log-rank test	0.9603	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	29	32
0	9 (31.0%)	13 (40.6%)
1	3 (10.3%)	2 (6.3%)
2	3 (10.3%)	1 (3.1%)
3	3 (10.3%)	2 (6.3%)
>=4	11 (37.9%)	14 (43.8%)
p-value from Interaction Test[c]	0.4062	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	64 (66.0%)	50 (59.5%)
Censored	33 (34.0%)	34 (40.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.4 (0.7, 1.5)
50%	3.1 (2.1, 5.8)	3.7 (2.1, 15.9)
75%	39.6 (15.2, NE)	42.0 (20.7, NE)
Survival probability (95% CI) at		
Month 6	39.9% (29.8%, 49.7%)	47.9% (36.4%, 58.4%)
Month 12	35.9% (26.1%, 45.8%)	44.7% (33.3%, 55.5%)
Month 18	34.4% (24.6%, 44.3%)	37.4% (26.1%, 48.6%)
Month 24	31.0% (21.3%, 41.2%)	35.0% (23.7%, 46.6%)
Month 30	31.0% (21.3%, 41.2%)	35.0% (23.7%, 46.6%)
Month 36	28.4% (18.6%, 39.1%)	31.9% (20.3%, 44.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.18 (0.810, 1.730)	
p-value of 2-sided stratified log-rank test	0.3745	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	64	50
0	40 (62.5%)	28 (56.0%)
1	10 (15.6%)	9 (18.0%)
2	7 (10.9%)	7 (14.0%)
3	5 (7.8%)	2 (4.0%)
>=4	2 (3.1%)	4 (8.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	67 (70.5%)	61 (61.0%)
Censored	28 (29.5%)	39 (39.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.4)	0.9 (0.8, 1.4)
50%	2.1 (1.4, 3.7)	4.4 (1.6, 9.3)
75%	21.9 (7.9, NE)	NE (16.7, NE)
Survival probability (95% CI) at		
Month 6	38.5% (28.3%, 48.5%)	47.8% (37.5%, 57.4%)
Month 12	31.3% (21.6%, 41.5%)	38.0% (27.8%, 48.2%)
Month 18	26.8% (17.5%, 36.9%)	32.1% (21.8%, 42.8%)
Month 24	18.6% (10.1%, 29.0%)	32.1% (21.8%, 42.8%)
Month 30	18.6% (10.1%, 29.0%)	32.1% (21.8%, 42.8%)
Month 36	12.4% (3.7%, 26.6%)	26.8% (14.8%, 40.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.19 (0.836, 1.696)	
p-value of 2-sided stratified log-rank test	0.3393	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	67	61
0	36 (53.7%)	31 (50.8%)
1	10 (14.9%)	8 (13.1%)
2	9 (13.4%)	7 (11.5%)
3	3 (4.5%)	6 (9.8%)
>=4	9 (13.4%)	9 (14.8%)
p-value from Interaction Test[c]	0.8388	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	79 (81.4%)	71 (84.5%)
Censored	18 (18.6%)	13 (15.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.3 (0.7, 1.5)
50%	3.1 (2.1, 5.6)	3.7 (2.1, 12.5)
75%	21.9 (8.0, 39.6)	19.8 (12.6, 31.9)
Survival probability (95% CI) at		
Month 6	37.9% (28.1%, 47.5%)	45.1% (34.2%, 55.5%)
Month 12	30.2% (21.3%, 39.7%)	40.1% (29.5%, 50.5%)
Month 18	26.8% (18.2%, 36.1%)	26.3% (17.3%, 36.2%)
Month 24	24.5% (16.2%, 33.6%)	20.1% (12.1%, 29.4%)
Month 30	19.8% (12.3%, 28.6%)	17.5% (10.1%, 26.5%)
Month 36	16.2% (9.1%, 25.2%)	13.3% (6.5%, 22.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.01 (0.727, 1.403)	
p-value of 2-sided stratified log-rank test	0.9463	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	79	71
0	55 (69.6%)	49 (69.0%)
1	10 (12.7%)	9 (12.7%)
2	7 (8.9%)	7 (9.9%)
3	5 (6.3%)	2 (2.8%)
>=4	2 (2.5%)	4 (5.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	79 (83.2%)	89 (89.0%)
Censored	16 (16.8%)	11 (11.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.1)	0.9 (0.8, 1.4)
50%	1.6 (1.4, 2.9)	4.4 (1.6, 9.3)
75%	16.7 (7.0, 22.4)	15.8 (11.2, 22.0)
Survival probability (95% CI) at		
Month 6	35.1% (25.5%, 44.9%)	48.9% (38.7%, 58.4%)
Month 12	28.8% (19.8%, 38.5%)	32.3% (23.2%, 41.6%)
Month 18	22.4% (14.2%, 31.8%)	20.8% (13.4%, 29.4%)
Month 24	14.1% (7.5%, 22.7%)	15.6% (9.2%, 23.5%)
Month 30	11.3% (5.4%, 19.5%)	14.5% (8.3%, 22.3%)
Month 36	6.6% (1.8%, 15.7%)	6.6% (2.4%, 13.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.09 (0.797, 1.481)	
p-value of 2-sided stratified log-rank test	0.6162	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	79	89
0	48 (60.8%)	59 (66.3%)
1	10 (12.7%)	8 (9.0%)
2	9 (11.4%)	7 (7.9%)
3	3 (3.8%)	6 (6.7%)
>=4	9 (11.4%)	9 (10.1%)
p-value from Interaction Test[c]	0.6934	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	27 (27.8%)	24 (28.6%)
Censored	70 (72.2%)	60 (71.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (2.1, NE)	3.5 (1.6, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	73.4% (63.2%, 81.2%)	71.5% (60.0%, 80.2%)
Month 12	72.1% (61.8%, 80.1%)	68.2% (56.3%, 77.5%)
Month 18	70.3% (59.6%, 78.7%)	68.2% (56.3%, 77.5%)
Month 24	70.3% (59.6%, 78.7%)	68.2% (56.3%, 77.5%)
Month 30	70.3% (59.6%, 78.7%)	68.2% (56.3%, 77.5%)
Month 36	70.3% (59.6%, 78.7%)	68.2% (56.3%, 77.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.12 (0.644, 1.946)	
p-value of 2-sided stratified log-rank test	0.6973	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	27	24
0	12 (44.4%)	10 (41.7%)
1	5 (18.5%)	0
2	2 (7.4%)	7 (29.2%)
3	1 (3.7%)	1 (4.2%)
>=4	7 (25.9%)	6 (25.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	22 (23.2%)	24 (24.0%)
Censored	73 (76.8%)	76 (76.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	9.8 (2.0, NE)	13.9 (1.6, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	75.5% (64.9%, 83.3%)	79.0% (69.3%, 85.9%)
Month 12	73.9% (63.1%, 82.1%)	76.1% (65.8%, 83.6%)
Month 18	73.9% (63.1%, 82.1%)	72.5% (61.4%, 80.9%)
Month 24	73.9% (63.1%, 82.1%)	72.5% (61.4%, 80.9%)
Month 30	73.9% (63.1%, 82.1%)	72.5% (61.4%, 80.9%)
Month 36	73.9% (63.1%, 82.1%)	72.5% (61.4%, 80.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.00 (0.551, 1.812)	
p-value of 2-sided stratified log-rank test	0.9933	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	22	24
0	10 (45.5%)	12 (50.0%)
1	1 (4.5%)	2 (8.3%)
2	2 (9.1%)	2 (8.3%)
3	3 (13.6%)	1 (4.2%)
>=4	6 (27.3%)	7 (29.2%)
p-value from Interaction Test[c]	0.9696	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	60 (61.9%)	47 (56.0%)
Censored	37 (38.1%)	37 (44.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.4, 2.9)	2.1 (1.4, 2.9)
50%	6.5 (3.7, 15.9)	8.3 (3.7, 22.8)
75%	NE (19.5, NE)	NE (22.8, NE)
Survival probability (95% CI) at		
Month 6	51.5% (40.9%, 61.2%)	57.0% (45.1%, 67.2%)
Month 12	42.5% (32.0%, 52.6%)	43.7% (31.7%, 55.0%)
Month 18	39.2% (28.7%, 49.5%)	43.7% (31.7%, 55.0%)
Month 24	31.7% (21.4%, 42.6%)	34.0% (22.0%, 46.3%)
Month 30	27.3% (17.1%, 38.5%)	28.9% (17.3%, 41.6%)
Month 36	27.3% (17.1%, 38.5%)	28.9% (17.3%, 41.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.10 (0.747, 1.635)	
p-value of 2-sided stratified log-rank test	0.6247	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	60	47
0	46 (76.7%)	32 (68.1%)
1	6 (10.0%)	9 (19.1%)
2	7 (11.7%)	4 (8.5%)
3	0	0
>=4	1 (1.7%)	2 (4.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	54 (56.8%)	53 (53.0%)
Censored	41 (43.2%)	47 (47.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 2.1)	3.8 (2.1, 5.6)
50%	4.5 (2.8, 17.9)	11.5 (7.9, 25.1)
75%	33.7 (21.9, NE)	NE (26.2, NE)
Survival probability (95% CI) at		
Month 6	48.6% (37.5%, 58.7%)	64.9% (54.0%, 73.8%)
Month 12	42.4% (31.4%, 53.0%)	45.8% (34.4%, 56.5%)
Month 18	38.5% (27.4%, 49.5%)	42.4% (30.9%, 53.3%)
Month 24	36.0% (24.7%, 47.3%)	40.3% (28.9%, 51.5%)
Month 30	32.4% (20.6%, 44.7%)	36.1% (24.7%, 47.6%)
Month 36	24.7% (12.8%, 38.6%)	28.4% (17.1%, 40.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.37 (0.930, 2.021)	
p-value of 2-sided stratified log-rank test	0.1109	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	54	53
0	39 (72.2%)	34 (64.2%)
1	9 (16.7%)	7 (13.2%)
2	1 (1.9%)	5 (9.4%)
3	1 (1.9%)	4 (7.5%)
>=4	4 (7.4%)	3 (5.7%)
p-value from Interaction Test[c]	0.4579	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	78 (80.4%)	66 (78.6%)
Censored	19 (19.6%)	18 (21.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.4, 2.9)	2.1 (1.4, 2.9)
50%	6.0 (3.7, 8.1)	7.4 (3.5, 11.1)
75%	21.9 (9.9, 32.6)	19.8 (13.2, 28.2)
Survival probability (95% CI) at		
Month 6	49.6% (39.2%, 59.1%)	52.7% (41.2%, 62.9%)
Month 12	33.7% (24.4%, 43.2%)	37.3% (26.8%, 47.8%)
Month 18	27.9% (19.2%, 37.2%)	28.3% (18.9%, 38.5%)
Month 24	22.8% (14.7%, 31.9%)	19.9% (11.8%, 29.5%)
Month 30	16.5% (9.5%, 25.1%)	15.6% (8.5%, 24.7%)
Month 36	14.8% (8.1%, 23.4%)	15.6% (8.5%, 24.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.06 (0.757, 1.486)	
p-value of 2-sided stratified log-rank test	0.7387	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	78	66
0	64 (82.1%)	51 (77.3%)
1	6 (7.7%)	9 (13.6%)
2	7 (9.0%)	4 (6.1%)
3	0	0
>=4	1 (1.3%)	2 (3.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	76 (80.0%)	83 (83.0%)
Censored	19 (20.0%)	17 (17.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.7)	3.8 (2.1, 5.6)
50%	4.0 (2.8, 8.8)	9.8 (7.4, 11.8)
75%	21.9 (12.7, 28.0)	25.0 (14.7, 33.1)
Survival probability (95% CI) at		
Month 6	45.7% (35.2%, 55.7%)	63.1% (52.7%, 71.8%)
Month 12	35.9% (25.9%, 45.9%)	38.6% (28.8%, 48.2%)
Month 18	29.5% (20.2%, 39.4%)	30.9% (21.9%, 40.3%)
Month 24	22.6% (14.1%, 32.2%)	25.2% (16.9%, 34.4%)
Month 30	15.5% (8.5%, 24.5%)	21.6% (13.8%, 30.6%)
Month 36	9.7% (4.2%, 17.8%)	13.5% (7.2%, 21.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.34 (0.972, 1.853)	
p-value of 2-sided stratified log-rank test	0.0730	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	76	83
0	61 (80.3%)	64 (77.1%)
1	9 (11.8%)	7 (8.4%)
2	1 (1.3%)	5 (6.0%)
3	1 (1.3%)	4 (4.8%)
>=4	4 (5.3%)	3 (3.6%)
p-value from Interaction Test[c]	0.3039	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	17 (17.5%)	19 (22.6%)
Censored	80 (82.5%)	65 (77.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (8.1, NE)	NE (1.4, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	84.1% (75.1%, 90.1%)	77.5% (66.6%, 85.2%)
Month 12	81.2% (71.4%, 88.0%)	75.9% (64.7%, 83.9%)
Month 18	81.2% (71.4%, 88.0%)	75.9% (64.7%, 83.9%)
Month 24	81.2% (71.4%, 88.0%)	75.9% (64.7%, 83.9%)
Month 30	81.2% (71.4%, 88.0%)	75.9% (64.7%, 83.9%)
Month 36	81.2% (71.4%, 88.0%)	75.9% (64.7%, 83.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.33 (0.681, 2.579)	
p-value of 2-sided stratified log-rank test	0.4086	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	17	19
0	4 (23.5%)	8 (42.1%)
1	5 (29.4%)	2 (10.5%)
2	2 (11.8%)	1 (5.3%)
3	3 (17.6%)	2 (10.5%)
>=4	3 (17.6%)	6 (31.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	17 (17.9%)	11 (11.0%)
Censored	78 (82.1%)	89 (89.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (2.2, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	80.2% (70.0%, 87.2%)	89.5% (81.4%, 94.2%)
Month 12	80.2% (70.0%, 87.2%)	88.1% (79.4%, 93.3%)
Month 18	80.2% (70.0%, 87.2%)	88.1% (79.4%, 93.3%)
Month 24	80.2% (70.0%, 87.2%)	88.1% (79.4%, 93.3%)
Month 30	80.2% (70.0%, 87.2%)	88.1% (79.4%, 93.3%)
Month 36	80.2% (70.0%, 87.2%)	88.1% (79.4%, 93.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.55 (0.256, 1.175)	
p-value of 2-sided stratified log-rank test	0.1138	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	17	11
0	4 (23.5%)	5 (45.5%)
1	3 (17.6%)	1 (9.1%)
2	1 (5.9%)	0
3	3 (17.6%)	2 (18.2%)
>=4	6 (35.3%)	3 (27.3%)
p-value from Interaction Test[c]	0.0900	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	47 (48.5%)	36 (42.9%)
Censored	50 (51.5%)	48 (57.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (1.2, 3.7)	4.4 (1.4, 7.2)
50%	18.9 (7.1, NE)	19.5 (8.5, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	61.8% (51.2%, 70.7%)	68.1% (56.2%, 77.4%)
Month 12	56.5% (45.6%, 66.0%)	61.8% (49.4%, 71.9%)
Month 18	53.5% (42.4%, 63.3%)	53.1% (39.9%, 64.7%)
Month 24	46.5% (35.1%, 57.2%)	46.3% (32.9%, 58.6%)
Month 30	44.5% (33.0%, 55.4%)	43.7% (30.3%, 56.4%)
Month 36	44.5% (33.0%, 55.4%)	43.7% (30.3%, 56.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.11 (0.715, 1.733)	
p-value of 2-sided stratified log-rank test	0.6363	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	47	36
0	29 (61.7%)	20 (55.6%)
1	10 (21.3%)	4 (11.1%)
2	4 (8.5%)	8 (22.2%)
3	1 (2.1%)	0
>=4	3 (6.4%)	4 (11.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	33 (34.7%)	34 (34.0%)
Censored	62 (65.3%)	66 (66.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	4.4 (2.2, 19.8)	9.0 (2.3, 19.0)
50%	NE (23.0, NE)	NE (20.8, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	72.1% (61.2%, 80.3%)	77.4% (67.4%, 84.7%)
Month 12	68.1% (56.9%, 76.9%)	68.9% (57.8%, 77.7%)
Month 18	66.4% (55.0%, 75.5%)	67.3% (55.9%, 76.3%)
Month 24	58.0% (45.3%, 68.8%)	59.4% (46.9%, 69.9%)
Month 30	58.0% (45.3%, 68.8%)	54.0% (40.4%, 65.7%)
Month 36	55.0% (41.6%, 66.5%)	54.0% (40.4%, 65.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.05 (0.646, 1.719)	
p-value of 2-sided stratified log-rank test	0.8318	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	33	34
0	21 (63.6%)	25 (73.5%)
1	4 (12.1%)	3 (8.8%)
2	3 (9.1%)	3 (8.8%)
3	1 (3.0%)	0
>=4	4 (12.1%)	3 (8.8%)
p-value from Interaction Test[c]	0.8039	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	69 (71.1%)	58 (69.0%)
Censored	28 (28.9%)	26 (31.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.9 (1.2, 3.7)	3.6 (1.4, 5.4)
50%	11.0 (4.9, 18.7)	13.4 (6.7, 17.7)
75%	40.6 (22.4, NE)	28.2 (19.0, NE)
Survival probability (95% CI) at		
Month 6	59.3% (48.8%, 68.4%)	62.7% (51.2%, 72.2%)
Month 12	48.5% (38.1%, 58.1%)	53.4% (41.8%, 63.7%)
Month 18	42.9% (32.7%, 52.6%)	38.3% (27.5%, 49.1%)
Month 24	34.5% (24.9%, 44.3%)	28.6% (18.9%, 39.1%)
Month 30	28.6% (19.6%, 38.2%)	24.3% (15.3%, 34.6%)
Month 36	25.2% (16.5%, 34.9%)	24.3% (15.3%, 34.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.04 (0.727, 1.486)	
p-value of 2-sided stratified log-rank test	0.8310	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	69	58
0	51 (73.9%)	42 (72.4%)
1	10 (14.5%)	4 (6.9%)
2	4 (5.8%)	8 (13.8%)
3	1 (1.4%)	0
>=4	3 (4.3%)	4 (6.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	56 (58.9%)	81 (81.0%)
Censored	39 (41.1%)	19 (19.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.9 (1.4, 7.1)	7.3 (2.3, 9.9)
50%	19.8 (13.0, 24.6)	16.3 (12.0, 19.8)
75%	NE (30.2, NE)	29.4 (22.1, 36.5)
Survival probability (95% CI) at		
Month 6	69.0% (58.4%, 77.5%)	75.5% (65.7%, 82.9%)
Month 12	63.2% (52.3%, 72.3%)	60.2% (49.8%, 69.1%)
Month 18	55.7% (44.7%, 65.4%)	45.7% (35.7%, 55.3%)
Month 24	41.2% (30.4%, 51.6%)	32.9% (23.7%, 42.4%)
Month 30	35.6% (25.3%, 46.1%)	25.0% (16.7%, 34.1%)
Month 36	32.3% (22.1%, 42.9%)	19.7% (12.1%, 28.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.76 (0.542, 1.080)	
p-value of 2-sided stratified log-rank test	0.1300	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	56	81
0	44 (78.6%)	72 (88.9%)
1	4 (7.1%)	3 (3.7%)
2	3 (5.4%)	3 (3.7%)
3	1 (1.8%)	0
>=4	4 (7.1%)	3 (3.7%)
p-value from Interaction Test[c]	0.2677	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	27 (27.8%)	25 (29.8%)
Censored	70 (72.2%)	59 (70.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	10.4 (2.1, NE)	2.9 (1.4, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	75.4% (65.3%, 82.9%)	73.2% (62.0%, 81.7%)
Month 12	73.8% (63.3%, 81.7%)	73.2% (62.0%, 81.7%)
Month 18	70.6% (59.6%, 79.1%)	71.5% (60.0%, 80.3%)
Month 24	68.7% (57.3%, 77.6%)	64.8% (51.8%, 75.1%)
Month 30	68.7% (57.3%, 77.6%)	64.8% (51.8%, 75.1%)
Month 36	68.7% (57.3%, 77.6%)	64.8% (51.8%, 75.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.12 (0.647, 1.926)	
p-value of 2-sided stratified log-rank test	0.7031	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	27	25
0	13 (48.1%)	11 (44.0%)
1	3 (11.1%)	3 (12.0%)
2	2 (7.4%)	4 (16.0%)
3	2 (7.4%)	1 (4.0%)
>=4	7 (25.9%)	6 (24.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	21 (22.1%)	16 (16.0%)
Censored	74 (77.9%)	84 (84.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	15.8 (1.6, NE)	NE (16.8, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	77.9% (67.5%, 85.3%)	84.4% (75.4%, 90.3%)
Month 12	76.4% (65.7%, 84.1%)	84.4% (75.4%, 90.3%)
Month 18	74.3% (63.0%, 82.6%)	82.5% (72.8%, 89.0%)
Month 24	74.3% (63.0%, 82.6%)	82.5% (72.8%, 89.0%)
Month 30	74.3% (63.0%, 82.6%)	82.5% (72.8%, 89.0%)
Month 36	74.3% (63.0%, 82.6%)	82.5% (72.8%, 89.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.72 (0.372, 1.380)	
p-value of 2-sided stratified log-rank test	0.3056	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	21	16
0	4 (19.0%)	4 (25.0%)
1	3 (14.3%)	2 (12.5%)
2	6 (28.6%)	0
3	0	3 (18.8%)
>=4	8 (38.1%)	7 (43.8%)
p-value from Interaction Test[c]	0.2572	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	78 (86.7%)	70 (80.5%)
Censored	12 (13.3%)	17 (19.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 1.0)
50%	1.5 (1.4, 2.2)	1.4 (1.3, 2.5)
75%	3.1 (2.8, 10.2)	4.9 (2.8, 15.7)
Survival probability (95% CI) at		
Month 6	18.2% (11.0%, 26.9%)	23.5% (15.0%, 33.2%)
Month 12	15.3% (8.5%, 23.8%)	21.4% (13.0%, 31.2%)
Month 18	13.6% (7.1%, 22.0%)	14.3% (6.7%, 24.5%)
Month 24	9.7% (4.1%, 18.1%)	14.3% (6.7%, 24.5%)
Month 30	9.7% (4.1%, 18.1%)	9.5% (3.4%, 19.4%)
Month 36	NE (NE, NE)	9.5% (3.4%, 19.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.09 (0.787, 1.510)	
p-value of 2-sided stratified log-rank test	0.5930	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	78	70
0	27 (34.6%)	23 (32.9%)
1	13 (16.7%)	9 (12.9%)
2	8 (10.3%)	5 (7.1%)
3	8 (10.3%)	6 (8.6%)
>=4	22 (28.2%)	27 (38.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	32 (91.4%)	26 (78.8%)
Censored	3 (8.6%)	7 (21.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (0.7, 0.9)	0.7 (0.7, 0.9)
50%	1.0 (0.8, 1.4)	1.4 (0.8, 3.5)
75%	2.1 (1.1, 3.5)	4.3 (1.5, 28.5)
Survival probability (95% CI) at		
Month 6	9.8% (2.6%, 22.8%)	23.3% (9.8%, 40.1%)
Month 12	4.9% (0.5%, 18.4%)	15.5% (5.0%, 31.4%)
Month 18	4.9% (0.5%, 18.4%)	11.6% (3.0%, 26.7%)
Month 24	4.9% (0.5%, 18.4%)	11.6% (3.0%, 26.7%)
Month 30	4.9% (0.5%, 18.4%)	7.8% (1.4%, 21.8%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.29 (0.752, 2.207)	
p-value of 2-sided stratified log-rank test	0.3221	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	32	26
0	10 (31.3%)	9 (34.6%)
1	3 (9.4%)	8 (30.8%)
2	3 (9.4%)	2 (7.7%)
3	4 (12.5%)	0
>=4	12 (37.5%)	7 (26.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	49 (73.1%)	51 (79.7%)
Censored	18 (26.9%)	13 (20.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.4)	0.8 (0.7, 1.0)
50%	2.1 (1.4, 2.3)	1.5 (1.0, 2.8)
75%	5.8 (2.6, NE)	7.1 (2.8, 20.7)
Survival probability (95% CI) at		
Month 6	24.8% (14.5%, 36.6%)	28.3% (17.7%, 39.9%)
Month 12	16.1% (7.1%, 28.4%)	20.8% (11.5%, 32.0%)
Month 18	12.9% (4.8%, 25.1%)	18.2% (9.3%, 29.5%)
Month 24	12.9% (4.8%, 25.1%)	12.1% (4.6%, 23.6%)
Month 30	12.9% (4.8%, 25.1%)	12.1% (4.6%, 23.6%)
Month 36	12.9% (4.8%, 25.1%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.01 (0.682, 1.505)	
p-value of 2-sided stratified log-rank test	0.9644	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	49	51
0	20 (40.8%)	23 (45.1%)
1	8 (16.3%)	7 (13.7%)
2	4 (8.2%)	4 (7.8%)
3	4 (8.2%)	4 (7.8%)
>=4	13 (26.5%)	13 (25.5%)
p-value from Interaction Test[c]	0.5216	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	82 (91.1%)	79 (90.8%)
Censored	8 (8.9%)	8 (9.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.0)	0.8 (0.7, 1.0)
50%	1.5 (1.4, 2.2)	1.5 (1.3, 2.5)
75%	3.1 (2.8, 8.0)	5.4 (2.8, 14.5)
Survival probability (95% CI) at		
Month 6	18.0% (10.8%, 26.6%)	24.4% (16.0%, 33.9%)
Month 12	14.1% (7.8%, 22.3%)	19.3% (11.7%, 28.4%)
Month 18	12.7% (6.7%, 20.8%)	11.1% (5.4%, 19.2%)
Month 24	8.5% (3.6%, 15.9%)	9.7% (4.4%, 17.5%)
Month 30	8.5% (3.6%, 15.9%)	5.6% (1.8%, 12.3%)
Month 36	NE (NE, NE)	5.6% (1.8%, 12.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.07 (0.783, 1.470)	
p-value of 2-sided stratified log-rank test	0.6535	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	82	79
0	31 (37.8%)	32 (40.5%)
1	13 (15.9%)	9 (11.4%)
2	8 (9.8%)	5 (6.3%)
3	8 (9.8%)	6 (7.6%)
>=4	22 (26.8%)	27 (34.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	33 (94.3%)	27 (81.8%)
Censored	2 (5.7%)	6 (18.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (0.7, 0.9)	0.7 (0.7, 0.9)
50%	1.0 (0.8, 1.4)	1.4 (0.8, 3.5)
75%	2.1 (1.1, 3.5)	4.2 (1.5, 12.6)
Survival probability (95% CI) at		
Month 6	9.8% (2.6%, 22.8%)	21.0% (8.5%, 37.1%)
Month 12	6.5% (1.2%, 18.6%)	14.0% (4.4%, 28.9%)
Month 18	3.3% (0.3%, 14.1%)	10.5% (2.7%, 24.6%)
Month 24	3.3% (0.3%, 14.1%)	10.5% (2.7%, 24.6%)
Month 30	3.3% (0.3%, 14.1%)	7.0% (1.2%, 20.0%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.29 (0.759, 2.184)	
p-value of 2-sided stratified log-rank test	0.3141	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	33	27
0	11 (33.3%)	10 (37.0%)
1	3 (9.1%)	8 (29.6%)
2	3 (9.1%)	2 (7.4%)
3	4 (12.1%)	0
>=4	12 (36.4%)	7 (25.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	60 (89.6%)	62 (96.9%)
Censored	7 (10.4%)	2 (3.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.1)	0.8 (0.7, 1.0)
50%	2.1 (1.4, 2.3)	1.5 (1.0, 2.8)
75%	5.5 (2.6, 8.4)	7.1 (2.8, 12.2)
Survival probability (95% CI) at		
Month 6	21.9% (12.7%, 32.6%)	28.1% (17.8%, 39.4%)
Month 12	10.3% (4.3%, 19.4%)	17.2% (9.2%, 27.3%)
Month 18	6.9% (2.3%, 15.1%)	10.9% (4.8%, 19.9%)
Month 24	6.9% (2.3%, 15.1%)	6.3% (2.0%, 14.0%)
Month 30	5.2% (1.4%, 12.8%)	4.2% (0.9%, 11.6%)
Month 36	5.2% (1.4%, 12.8%)	0 (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.05 (0.733, 1.502)	
p-value of 2-sided stratified log-rank test	0.8011	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	60	62
0	31 (51.7%)	34 (54.8%)
1	8 (13.3%)	7 (11.3%)
2	4 (6.7%)	4 (6.5%)
3	4 (6.7%)	4 (6.5%)
>=4	13 (21.7%)	13 (21.0%)
p-value from Interaction Test[c]	0.5062	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	58 (64.4%)	59 (67.8%)
Censored	32 (35.6%)	28 (32.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	0.9 (0.8, 1.4)
50%	3.7 (2.3, 8.3)	5.3 (1.9, 9.8)
75%	NE (8.7, NE)	29.2 (10.6, NE)
Survival probability (95% CI) at		
Month 6	46.5% (35.6%, 56.7%)	46.1% (35.0%, 56.4%)
Month 12	30.9% (20.7%, 41.6%)	31.7% (21.3%, 42.6%)
Month 18	29.0% (18.9%, 39.8%)	26.6% (16.8%, 37.4%)
Month 24	26.7% (16.8%, 37.7%)	26.6% (16.8%, 37.4%)
Month 30	26.7% (16.8%, 37.7%)	23.6% (13.8%, 35.0%)
Month 36	26.7% (16.8%, 37.7%)	23.6% (13.8%, 35.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.04 (0.722, 1.496)	
p-value of 2-sided stratified log-rank test	0.8320	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	58	59
0	34 (58.6%)	29 (49.2%)
1	12 (20.7%)	12 (20.3%)
2	1 (1.7%)	6 (10.2%)
3	2 (3.4%)	2 (3.4%)
>=4	9 (15.5%)	10 (16.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	19 (54.3%)	17 (51.5%)
Censored	16 (45.7%)	16 (48.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.8, 7.0)	2.1 (0.7, 5.2)
50%	12.6 (3.5, NE)	7.1 (2.8, NE)
75%	NE (20.0, NE)	NE (8.3, NE)
Survival probability (95% CI) at		
Month 6	61.6% (43.2%, 75.7%)	52.9% (32.5%, 69.6%)
Month 12	51.7% (33.5%, 67.2%)	44.0% (24.6%, 61.9%)
Month 18	48.0% (30.0%, 64.0%)	39.6% (20.9%, 57.9%)
Month 24	40.0% (22.6%, 56.8%)	35.2% (17.4%, 53.7%)
Month 30	40.0% (22.6%, 56.8%)	35.2% (17.4%, 53.7%)
Month 36	40.0% (22.6%, 56.8%)	35.2% (17.4%, 53.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.08 (0.550, 2.135)	
p-value of 2-sided stratified log-rank test	0.8192	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	19	17
0	11 (57.9%)	6 (35.3%)
1	3 (15.8%)	2 (11.8%)
2	1 (5.3%)	5 (29.4%)
3	2 (10.5%)	1 (5.9%)
>=4	2 (10.5%)	3 (17.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	41 (61.2%)	41 (64.1%)
Censored	26 (38.8%)	23 (35.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.1 (0.8, 1.8)	1.4 (0.8, 1.6)
50%	3.7 (1.9, 8.5)	4.9 (1.6, 11.1)
75%	22.0 (8.5, NE)	NE (11.4, NE)
Survival probability (95% CI) at		
Month 6	46.7% (33.7%, 58.7%)	43.7% (31.0%, 55.7%)
Month 12	33.6% (21.3%, 46.4%)	35.5% (23.2%, 47.9%)
Month 18	29.9% (17.4%, 43.4%)	28.8% (17.3%, 41.3%)
Month 24	21.3% (9.6%, 36.2%)	28.8% (17.3%, 41.3%)
Month 30	21.3% (9.6%, 36.2%)	28.8% (17.3%, 41.3%)
Month 36	21.3% (9.6%, 36.2%)	28.8% (17.3%, 41.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.89 (0.575, 1.372)	
p-value of 2-sided stratified log-rank test	0.5992	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	41	41
0	20 (48.8%)	14 (34.1%)
1	8 (19.5%)	9 (22.0%)
2	4 (9.8%)	7 (17.1%)
3	1 (2.4%)	2 (4.9%)
>=4	8 (19.5%)	9 (22.0%)
p-value from Interaction Test[c]	0.8096	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	62 (68.9%)	56 (64.4%)
Censored	28 (31.1%)	31 (35.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 1.5)	1.2 (0.8, 1.7)
50%	3.4 (2.3, 4.7)	5.6 (2.9, 11.6)
75%	24.1 (17.0, NE)	30.4 (13.4, NE)
Survival probability (95% CI) at		
Month 6	38.8% (28.4%, 49.0%)	47.2% (36.1%, 57.6%)
Month 12	37.4% (27.1%, 47.7%)	38.4% (27.3%, 49.5%)
Month 18	34.1% (23.9%, 44.5%)	31.9% (20.9%, 43.5%)
Month 24	26.6% (16.8%, 37.4%)	31.9% (20.9%, 43.5%)
Month 30	22.2% (12.8%, 33.1%)	25.6% (14.5%, 38.2%)
Month 36	22.2% (12.8%, 33.1%)	17.5% (7.2%, 31.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.04 (0.725, 1.500)	
p-value of 2-sided stratified log-rank test	0.8112	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	62	56
0	40 (64.5%)	37 (66.1%)
1	12 (19.4%)	9 (16.1%)
2	5 (8.1%)	3 (5.4%)
3	4 (6.5%)	4 (7.1%)
>=4	1 (1.6%)	3 (5.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	23 (65.7%)	23 (69.7%)
Censored	12 (34.3%)	10 (30.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.7, 1.5)	1.1 (0.7, 2.1)
50%	4.0 (1.4, 42.5)	2.8 (1.4, 12.8)
75%	42.5 (8.3, NE)	22.8 (3.3, NE)
Survival probability (95% CI) at		
Month 6	44.5% (27.6%, 60.1%)	38.1% (21.0%, 55.1%)
Month 12	38.6% (22.6%, 54.3%)	34.7% (18.3%, 51.6%)
Month 18	38.6% (22.6%, 54.3%)	30.8% (15.3%, 47.8%)
Month 24	38.6% (22.6%, 54.3%)	23.1% (9.7%, 39.8%)
Month 30	38.6% (22.6%, 54.3%)	23.1% (9.7%, 39.8%)
Month 36	33.8% (17.9%, 50.3%)	17.3% (5.5%, 34.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.79 (0.437, 1.412)	
p-value of 2-sided stratified log-rank test	0.4093	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	23	23
0	14 (60.9%)	17 (73.9%)
1	5 (21.7%)	3 (13.0%)
2	3 (13.0%)	3 (13.0%)
3	1 (4.3%)	0
>=4	0	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	43 (64.2%)	33 (51.6%)
Censored	24 (35.8%)	31 (48.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.6)	2.1 (0.8, 3.5)
50%	3.1 (2.0, 4.6)	12.5 (3.5, NE)
75%	40.2 (4.6, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	35.0% (23.1%, 47.1%)	58.9% (45.4%, 70.0%)
Month 12	32.5% (20.7%, 44.8%)	50.5% (36.9%, 62.7%)
Month 18	29.5% (17.8%, 42.2%)	40.1% (26.3%, 53.4%)
Month 24	29.5% (17.8%, 42.2%)	40.1% (26.3%, 53.4%)
Month 30	25.3% (13.5%, 39.0%)	40.1% (26.3%, 53.4%)
Month 36	25.3% (13.5%, 39.0%)	40.1% (26.3%, 53.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.57 (0.998, 2.484)	
p-value of 2-sided stratified log-rank test	0.0492	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	43	33
0	31 (72.1%)	24 (72.7%)
1	2 (4.7%)	5 (15.2%)
2	4 (9.3%)	1 (3.0%)
3	2 (4.7%)	1 (3.0%)
>=4	4 (9.3%)	2 (6.1%)
p-value from Interaction Test[c]	0.1410	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	76 (84.4%)	77 (88.5%)
Censored	14 (15.6%)	10 (11.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 1.6)	1.2 (0.8, 1.7)
50%	3.4 (2.3, 4.7)	5.7 (2.9, 11.1)
75%	19.9 (9.7, 28.0)	16.3 (12.6, 20.0)
Survival probability (95% CI) at		
Month 6	38.4% (28.2%, 48.4%)	48.8% (37.9%, 58.9%)
Month 12	32.4% (22.9%, 42.3%)	35.5% (25.4%, 45.6%)
Month 18	29.9% (20.6%, 39.8%)	22.0% (13.8%, 31.4%)
Month 24	19.9% (12.1%, 29.0%)	13.2% (6.9%, 21.5%)
Month 30	14.6% (7.9%, 23.2%)	10.5% (5.0%, 18.4%)
Month 36	13.0% (6.6%, 21.4%)	7.2% (2.7%, 14.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.94 (0.680, 1.290)	
p-value of 2-sided stratified log-rank test	0.6953	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	76	77
0	54 (71.1%)	58 (75.3%)
1	12 (15.8%)	9 (11.7%)
2	5 (6.6%)	3 (3.9%)
3	4 (5.3%)	4 (5.2%)
>=4	1 (1.3%)	3 (3.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	24 (68.6%)	25 (75.8%)
Censored	11 (31.4%)	8 (24.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.7, 1.5)	1.1 (0.7, 2.1)
50%	4.0 (1.4, 30.8)	2.8 (1.4, 12.5)
75%	42.5 (8.3, NE)	19.7 (3.3, NE)
Survival probability (95% CI) at		
Month 6	44.5% (27.6%, 60.1%)	38.1% (21.0%, 55.1%)
Month 12	38.6% (22.6%, 54.3%)	34.7% (18.3%, 51.6%)
Month 18	35.1% (19.6%, 51.0%)	27.7% (13.1%, 44.5%)
Month 24	35.1% (19.6%, 51.0%)	20.8% (8.5%, 36.9%)
Month 30	35.1% (19.6%, 51.0%)	20.8% (8.5%, 36.9%)
Month 36	30.7% (15.7%, 47.1%)	12.5% (3.4%, 27.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.75 (0.427, 1.329)	
p-value of 2-sided stratified log-rank test	0.3181	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	24	25
0	15 (62.5%)	19 (76.0%)
1	5 (20.8%)	3 (12.0%)
2	3 (12.5%)	3 (12.0%)
3	1 (4.2%)	0
>=4	0	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	57 (85.1%)	50 (78.1%)
Censored	10 (14.9%)	14 (21.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.5)	1.8 (0.8, 3.5)
50%	3.1 (1.6, 4.6)	9.0 (3.5, 12.2)
75%	13.4 (4.9, 25.3)	19.0 (12.5, NE)
Survival probability (95% CI) at		
Month 6	32.6% (21.5%, 44.1%)	56.3% (43.3%, 67.4%)
Month 12	25.4% (15.3%, 36.7%)	38.6% (26.8%, 50.4%)
Month 18	20.0% (11.0%, 30.9%)	25.8% (15.7%, 37.0%)
Month 24	18.1% (9.6%, 28.9%)	22.3% (12.9%, 33.3%)
Month 30	10.9% (4.5%, 20.5%)	20.3% (11.2%, 31.2%)
Month 36	8.7% (3.1%, 18.0%)	20.3% (11.2%, 31.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.46 (0.997, 2.143)	
p-value of 2-sided stratified log-rank test	0.0506	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	57	50
0	45 (78.9%)	41 (82.0%)
1	2 (3.5%)	5 (10.0%)
2	4 (7.0%)	1 (2.0%)
3	2 (3.5%)	1 (2.0%)
>=4	4 (7.0%)	2 (4.0%)
p-value from Interaction Test[c]	0.0933	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	22 (24.4%)	20 (23.0%)
Censored	68 (75.6%)	67 (77.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	9.5 (1.4, NE)	NE (1.4, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	75.6% (65.0%, 83.4%)	77.3% (66.8%, 84.9%)
Month 12	74.0% (63.1%, 82.1%)	75.6% (64.6%, 83.6%)
Month 18	74.0% (63.1%, 82.1%)	75.6% (64.6%, 83.6%)
Month 24	74.0% (63.1%, 82.1%)	75.6% (64.6%, 83.6%)
Month 30	74.0% (63.1%, 82.1%)	75.6% (64.6%, 83.6%)
Month 36	74.0% (63.1%, 82.1%)	75.6% (64.6%, 83.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.89 (0.486, 1.633)	
p-value of 2-sided stratified log-rank test	0.7132	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	22	20
0	4 (18.2%)	7 (35.0%)
1	5 (22.7%)	1 (5.0%)
2	2 (9.1%)	4 (20.0%)
3	2 (9.1%)	3 (15.0%)
>=4	9 (40.9%)	5 (25.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	9 (25.7%)	9 (27.3%)
Censored	26 (74.3%)	24 (72.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	35.7 (1.6, NE)	3.1 (0.7, NE)
50%	NE (35.7, NE)	NE (6.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	76.5% (58.4%, 87.5%)	72.8% (52.9%, 85.4%)
Month 12	76.5% (58.4%, 87.5%)	68.3% (47.5%, 82.2%)
Month 18	76.5% (58.4%, 87.5%)	68.3% (47.5%, 82.2%)
Month 24	76.5% (58.4%, 87.5%)	68.3% (47.5%, 82.2%)
Month 30	76.5% (58.4%, 87.5%)	68.3% (47.5%, 82.2%)
Month 36	63.7% (33.2%, 83.2%)	68.3% (47.5%, 82.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.23 (0.474, 3.208)	
p-value of 2-sided stratified log-rank test	0.6826	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	9	9
0	5 (55.6%)	3 (33.3%)
1	1 (11.1%)	2 (22.2%)
2	0	1 (11.1%)
3	0	1 (11.1%)
>=4	3 (33.3%)	2 (22.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	16 (23.9%)	14 (21.9%)
Censored	51 (76.1%)	50 (78.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	5.7 (1.4, NE)	NE (0.9, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	73.2% (59.9%, 82.6%)	77.3% (64.6%, 85.9%)
Month 12	73.2% (59.9%, 82.6%)	77.3% (64.6%, 85.9%)
Month 18	73.2% (59.9%, 82.6%)	77.3% (64.6%, 85.9%)
Month 24	73.2% (59.9%, 82.6%)	77.3% (64.6%, 85.9%)
Month 30	73.2% (59.9%, 82.6%)	77.3% (64.6%, 85.9%)
Month 36	73.2% (59.9%, 82.6%)	77.3% (64.6%, 85.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.92 (0.447, 1.881)	
p-value of 2-sided stratified log-rank test	0.8087	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	16	14
0	8 (50.0%)	3 (21.4%)
1	1 (6.3%)	1 (7.1%)
2	2 (12.5%)	1 (7.1%)
3	2 (12.5%)	1 (7.1%)
>=4	3 (18.8%)	8 (57.1%)
p-value from Interaction Test[c]	0.7456	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	61 (67.8%)	58 (66.7%)
Censored	29 (32.2%)	29 (33.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.2)	1.4 (0.9, 2.2)
50%	4.7 (2.8, 10.3)	4.4 (3.3, 7.2)
75%	23.2 (11.7, NE)	20.8 (11.2, NE)
Survival probability (95% CI) at		
Month 6	47.1% (36.1%, 57.3%)	47.1% (36.0%, 57.4%)
Month 12	33.4% (23.0%, 44.1%)	34.6% (24.0%, 45.5%)
Month 18	31.9% (21.7%, 42.6%)	28.5% (18.2%, 39.7%)
Month 24	23.6% (14.0%, 34.7%)	22.2% (11.9%, 34.4%)
Month 30	23.6% (14.0%, 34.7%)	22.2% (11.9%, 34.4%)
Month 36	17.5% (8.3%, 29.4%)	16.6% (6.4%, 31.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.93 (0.645, 1.333)	
p-value of 2-sided stratified log-rank test	0.6829	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	61	58
0	35 (57.4%)	26 (44.8%)
1	6 (9.8%)	12 (20.7%)
2	11 (18.0%)	8 (13.8%)
3	1 (1.6%)	0
>=4	8 (13.1%)	12 (20.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	31 (88.6%)	22 (66.7%)
Censored	4 (11.4%)	11 (33.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.9 (0.7, 2.8)
50%	1.4 (0.9, 3.0)	3.5 (1.1, 7.1)
75%	4.6 (1.6, 20.9)	12.9 (5.6, NE)
Survival probability (95% CI) at		
Month 6	21.0% (9.3%, 35.8%)	38.1% (20.8%, 55.3%)
Month 12	17.5% (6.9%, 32.1%)	26.7% (12.1%, 43.8%)
Month 18	14.0% (4.7%, 28.2%)	22.9% (9.5%, 39.7%)
Month 24	10.5% (2.8%, 24.0%)	22.9% (9.5%, 39.7%)
Month 30	10.5% (2.8%, 24.0%)	22.9% (9.5%, 39.7%)
Month 36	5.2% (0.5%, 19.4%)	22.9% (9.5%, 39.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.55 (0.889, 2.711)	
p-value of 2-sided stratified log-rank test	0.1108	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	31	22
0	16 (51.6%)	11 (50.0%)
1	3 (9.7%)	5 (22.7%)
2	6 (19.4%)	2 (9.1%)
3	1 (3.2%)	0
>=4	5 (16.1%)	4 (18.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	43 (64.2%)	47 (73.4%)
Censored	24 (35.8%)	17 (26.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 2.8)	0.9 (0.8, 2.1)
50%	5.6 (2.8, 11.5)	3.5 (2.1, 7.0)
75%	17.7 (11.5, NE)	11.3 (7.1, 21.7)
Survival probability (95% CI) at		
Month 6	47.9% (34.7%, 59.9%)	41.3% (28.6%, 53.5%)
Month 12	36.5% (23.7%, 49.4%)	24.3% (13.6%, 36.6%)
Month 18	21.7% (10.5%, 35.6%)	21.6% (11.3%, 34.0%)
Month 24	18.1% (7.7%, 32.1%)	9.0% (2.0%, 22.8%)
Month 30	18.1% (7.7%, 32.1%)	9.0% (2.0%, 22.8%)
Month 36	12.1% (3.0%, 27.8%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.77 (0.504, 1.166)	
p-value of 2-sided stratified log-rank test	0.2151	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	43	47
0	26 (60.5%)	26 (55.3%)
1	2 (4.7%)	11 (23.4%)
2	6 (14.0%)	3 (6.4%)
3	3 (7.0%)	3 (6.4%)
>=4	6 (14.0%)	4 (8.5%)
p-value from Interaction Test[c]	0.0666	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	74 (82.2%)	77 (88.5%)
Censored	16 (17.8%)	10 (11.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.2)	1.4 (0.9, 2.3)
50%	4.7 (2.8, 8.8)	5.4 (3.4, 7.3)
75%	19.2 (10.3, 29.0)	14.9 (9.8, 19.9)
Survival probability (95% CI) at		
Month 6	46.1% (35.4%, 56.2%)	47.7% (36.8%, 57.7%)
Month 12	30.8% (21.2%, 40.9%)	32.0% (22.3%, 42.0%)
Month 18	26.9% (17.8%, 36.8%)	19.2% (11.5%, 28.4%)
Month 24	16.2% (9.0%, 25.1%)	9.8% (4.5%, 17.7%)
Month 30	14.8% (8.0%, 23.6%)	9.8% (4.5%, 17.7%)
Month 36	9.9% (4.3%, 18.2%)	5.9% (1.8%, 13.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.88 (0.638, 1.216)	
p-value of 2-sided stratified log-rank test	0.4393	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	74	77
0	48 (64.9%)	45 (58.4%)
1	6 (8.1%)	12 (15.6%)
2	11 (14.9%)	8 (10.4%)
3	1 (1.4%)	0
>=4	8 (10.8%)	12 (15.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	32 (91.4%)	24 (72.7%)
Censored	3 (8.6%)	9 (27.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.9 (0.7, 2.8)
50%	1.4 (0.9, 3.0)	3.6 (1.1, 7.1)
75%	4.6 (1.6, 20.9)	7.4 (4.6, NE)
Survival probability (95% CI) at		
Month 6	21.0% (9.3%, 35.8%)	33.3% (17.5%, 50.0%)
Month 12	18.0% (7.3%, 32.4%)	23.3% (10.3%, 39.4%)
Month 18	12.0% (3.8%, 25.2%)	20.0% (8.1%, 35.6%)
Month 24	9.0% (2.3%, 21.4%)	20.0% (8.1%, 35.6%)
Month 30	9.0% (2.3%, 21.4%)	20.0% (8.1%, 35.6%)
Month 36	4.5% (0.4%, 17.2%)	20.0% (8.1%, 35.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.46 (0.852, 2.506)	
p-value of 2-sided stratified log-rank test	0.1565	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	32	24
0	17 (53.1%)	13 (54.2%)
1	3 (9.4%)	5 (20.8%)
2	6 (18.8%)	2 (8.3%)
3	1 (3.1%)	0
>=4	5 (15.6%)	4 (16.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	59 (88.1%)	62 (96.9%)
Censored	8 (11.9%)	2 (3.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.8)	0.9 (0.8, 2.1)
50%	4.6 (2.8, 7.6)	3.5 (2.1, 6.9)
75%	13.2 (8.4, 18.0)	11.2 (7.0, 15.8)
Survival probability (95% CI) at		
Month 6	43.4% (31.0%, 55.1%)	39.1% (27.2%, 50.7%)
Month 12	28.4% (17.9%, 39.9%)	21.2% (12.1%, 31.9%)
Month 18	15.1% (7.5%, 25.1%)	13.0% (6.1%, 22.6%)
Month 24	10.0% (4.1%, 19.1%)	4.9% (1.3%, 12.3%)
Month 30	6.7% (2.2%, 14.8%)	1.6% (0.1%, 7.7%)
Month 36	4.5% (1.0%, 12.4%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.81 (0.563, 1.159)	
p-value of 2-sided stratified log-rank test	0.2487	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	59	62
0	42 (71.2%)	41 (66.1%)
1	2 (3.4%)	11 (17.7%)
2	6 (10.2%)	3 (4.8%)
3	3 (5.1%)	3 (4.8%)
>=4	6 (10.2%)	4 (6.5%)
p-value from Interaction Test[c]	0.0746	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	62 (68.9%)	45 (51.7%)
Censored	28 (31.1%)	42 (48.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.8)	0.8 (0.7, 1.4)
50%	1.4 (1.0, 2.6)	7.1 (1.4, NE)
75%	NE (3.8, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	33.0% (23.3%, 43.1%)	50.7% (39.7%, 60.8%)
Month 12	28.5% (19.1%, 38.6%)	49.3% (38.2%, 59.4%)
Month 18	26.8% (17.6%, 36.9%)	45.0% (33.5%, 55.9%)
Month 24	26.8% (17.6%, 36.9%)	45.0% (33.5%, 55.9%)
Month 30	26.8% (17.6%, 36.9%)	45.0% (33.5%, 55.9%)
Month 36	26.8% (17.6%, 36.9%)	45.0% (33.5%, 55.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.66 (0.448, 0.970)	
p-value of 2-sided stratified log-rank test	0.0345	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	62	45
0	29 (46.8%)	18 (40.0%)
1	6 (9.7%)	5 (11.1%)
2	8 (12.9%)	6 (13.3%)
3	2 (3.2%)	3 (6.7%)
>=4	17 (27.4%)	13 (28.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	20 (57.1%)	17 (51.5%)
Censored	15 (42.9%)	16 (48.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.7, 2.2)	0.8 (0.7, 1.4)
50%	7.0 (1.4, NE)	4.7 (0.8, NE)
75%	NE (19.1, NE)	NE (5.2, NE)
Survival probability (95% CI) at		
Month 6	52.9% (34.9%, 68.0%)	43.6% (24.8%, 60.9%)
Month 12	49.8% (32.1%, 65.2%)	39.2% (21.1%, 57.0%)
Month 18	42.7% (25.5%, 58.8%)	39.2% (21.1%, 57.0%)
Month 24	38.8% (22.0%, 55.3%)	39.2% (21.1%, 57.0%)
Month 30	38.8% (22.0%, 55.3%)	39.2% (21.1%, 57.0%)
Month 36	38.8% (22.0%, 55.3%)	39.2% (21.1%, 57.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.17 (0.606, 2.266)	
p-value of 2-sided stratified log-rank test	0.6647	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	20	17
0	8 (40.0%)	5 (29.4%)
1	5 (25.0%)	6 (35.3%)
2	3 (15.0%)	1 (5.9%)
3	0	1 (5.9%)
>=4	4 (20.0%)	4 (23.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	40 (59.7%)	32 (50.0%)
Censored	27 (40.3%)	32 (50.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.4 (0.8, 1.5)
50%	2.1 (1.4, 4.5)	10.2 (1.6, NE)
75%	NE (4.5, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	36.8% (24.8%, 48.9%)	51.1% (38.0%, 62.7%)
Month 12	34.4% (22.4%, 46.7%)	48.9% (35.8%, 60.8%)
Month 18	34.4% (22.4%, 46.7%)	46.4% (33.1%, 58.6%)
Month 24	34.4% (22.4%, 46.7%)	46.4% (33.1%, 58.6%)
Month 30	34.4% (22.4%, 46.7%)	46.4% (33.1%, 58.6%)
Month 36	30.1% (17.5%, 43.6%)	46.4% (33.1%, 58.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.65 (0.408, 1.037)	
p-value of 2-sided stratified log-rank test	0.0712	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	40	32
0	21 (52.5%)	11 (34.4%)
1	6 (15.0%)	7 (21.9%)
2	3 (7.5%)	3 (9.4%)
3	2 (5.0%)	0
>=4	8 (20.0%)	11 (34.4%)
p-value from Interaction Test[c]	0.3332	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	63 (70.0%)	57 (65.5%)
Censored	27 (30.0%)	30 (34.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 1.6)	1.6 (1.0, 2.2)
50%	3.4 (2.1, 6.3)	3.7 (2.8, 9.2)
75%	23.1 (12.9, NE)	24.7 (10.0, NE)
Survival probability (95% CI) at		
Month 6	40.4% (30.1%, 50.5%)	42.5% (31.6%, 53.0%)
Month 12	36.1% (26.0%, 46.3%)	33.8% (23.1%, 44.8%)
Month 18	28.9% (19.0%, 39.5%)	33.8% (23.1%, 44.8%)
Month 24	24.9% (15.4%, 35.7%)	28.4% (17.5%, 40.3%)
Month 30	22.1% (12.7%, 33.3%)	17.8% (7.8%, 31.0%)
Month 36	NE (NE, NE)	17.8% (7.8%, 31.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.07 (0.749, 1.542)	
p-value of 2-sided stratified log-rank test	0.7203	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	63	57
0	34 (54.0%)	27 (47.4%)
1	9 (14.3%)	10 (17.5%)
2	7 (11.1%)	4 (7.0%)
3	4 (6.3%)	5 (8.8%)
>=4	9 (14.3%)	11 (19.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	20 (57.1%)	24 (72.7%)
Censored	15 (42.9%)	9 (27.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 2.8)	1.4 (0.7, 1.6)
50%	4.1 (2.2, NE)	2.8 (1.4, 6.9)
75%	NE (29.7, NE)	10.9 (3.5, NE)
Survival probability (95% CI) at		
Month 6	49.8% (32.1%, 65.2%)	34.0% (17.6%, 51.2%)
Month 12	42.6% (25.4%, 58.8%)	22.7% (9.4%, 39.4%)
Month 18	42.6% (25.4%, 58.8%)	18.9% (7.0%, 35.2%)
Month 24	42.6% (25.4%, 58.8%)	18.9% (7.0%, 35.2%)
Month 30	35.5% (17.5%, 54.1%)	18.9% (7.0%, 35.2%)
Month 36	35.5% (17.5%, 54.1%)	0 (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.66 (0.358, 1.209)	
p-value of 2-sided stratified log-rank test	0.1477	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	20	24
0	8 (40.0%)	13 (54.2%)
1	2 (10.0%)	3 (12.5%)
2	0	2 (8.3%)
3	2 (10.0%)	4 (16.7%)
>=4	8 (40.0%)	2 (8.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	37 (55.2%)	40 (62.5%)
Censored	30 (44.8%)	24 (37.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.2 (0.9, 3.0)	2.1 (0.8, 3.4)
50%	6.0 (3.4, 27.9)	6.9 (3.5, 12.5)
75%	30.2 (25.3, NE)	NE (12.5, NE)
Survival probability (95% CI) at		
Month 6	51.1% (37.7%, 63.0%)	52.6% (39.4%, 64.2%)
Month 12	46.6% (33.2%, 59.0%)	38.4% (25.7%, 50.9%)
Month 18	40.6% (26.8%, 54.0%)	33.4% (21.0%, 46.3%)
Month 24	40.6% (26.8%, 54.0%)	30.4% (18.1%, 43.5%)
Month 30	27.1% (13.2%, 43.1%)	25.3% (12.7%, 40.1%)
Month 36	21.7% (8.6%, 38.5%)	25.3% (12.7%, 40.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.89 (0.564, 1.400)	
p-value of 2-sided stratified log-rank test	0.6101	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	37	40
0	23 (62.2%)	20 (50.0%)
1	6 (16.2%)	10 (25.0%)
2	4 (10.8%)	1 (2.5%)
3	0	3 (7.5%)
>=4	4 (10.8%)	6 (15.0%)
p-value from Interaction Test[c]	0.3154	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	77 (85.6%)	74 (85.1%)
Censored	13 (14.4%)	13 (14.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 1.6)	1.6 (1.0, 2.5)
50%	3.4 (2.1, 4.4)	3.8 (2.8, 8.2)
75%	14.9 (6.9, 28.0)	17.3 (9.6, 23.1)
Survival probability (95% CI) at		
Month 6	38.8% (28.7%, 48.8%)	42.5% (31.9%, 52.6%)
Month 12	30.4% (21.1%, 40.3%)	29.6% (20.2%, 39.7%)
Month 18	22.8% (14.5%, 32.3%)	24.3% (15.6%, 34.1%)
Month 24	19.0% (11.4%, 28.1%)	15.5% (8.4%, 24.6%)
Month 30	13.6% (7.2%, 22.1%)	7.8% (3.0%, 15.6%)
Month 36	NE (NE, NE)	7.8% (3.0%, 15.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.03 (0.746, 1.422)	
p-value of 2-sided stratified log-rank test	0.8867	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	77	74
0	48 (62.3%)	44 (59.5%)
1	9 (11.7%)	10 (13.5%)
2	7 (9.1%)	4 (5.4%)
3	4 (5.2%)	5 (6.8%)
>=4	9 (11.7%)	11 (14.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	25 (71.4%)	25 (75.8%)
Censored	10 (28.6%)	8 (24.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 2.8)	1.4 (0.7, 1.6)
50%	4.1 (2.2, 22.4)	2.8 (1.4, 6.9)
75%	29.7 (13.2, NE)	10.9 (3.5, NE)
Survival probability (95% CI) at		
Month 6	49.8% (32.1%, 65.2%)	34.0% (17.6%, 51.2%)
Month 12	43.3% (26.3%, 59.3%)	22.7% (9.4%, 39.4%)
Month 18	36.4% (20.3%, 52.7%)	18.9% (7.0%, 35.2%)
Month 24	32.3% (16.8%, 48.9%)	18.9% (7.0%, 35.2%)
Month 30	24.2% (10.6%, 40.9%)	18.9% (7.0%, 35.2%)
Month 36	19.4% (7.1%, 36.2%)	9.4% (1.0%, 30.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.77 (0.437, 1.366)	
p-value of 2-sided stratified log-rank test	0.3381	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	25	25
0	13 (52.0%)	14 (56.0%)
1	2 (8.0%)	3 (12.0%)
2	0	2 (8.0%)
3	2 (8.0%)	4 (16.0%)
>=4	8 (32.0%)	2 (8.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	54 (80.6%)	55 (85.9%)
Censored	13 (19.4%)	9 (14.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.2 (0.9, 2.9)	1.9 (0.8, 3.4)
50%	4.3 (3.0, 9.6)	6.4 (3.5, 9.6)
75%	18.9 (11.3, 27.9)	15.8 (10.0, 28.2)
Survival probability (95% CI) at		
Month 6	46.2% (33.5%, 57.9%)	51.6% (38.8%, 63.0%)
Month 12	35.9% (24.1%, 47.8%)	32.3% (21.2%, 43.8%)
Month 18	27.2% (16.6%, 38.8%)	22.6% (13.2%, 33.5%)
Month 24	21.6% (12.1%, 32.8%)	15.8% (8.0%, 26.0%)
Month 30	11.8% (4.9%, 21.8%)	11.3% (4.7%, 21.2%)
Month 36	9.4% (3.4%, 19.2%)	11.3% (4.7%, 21.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.96 (0.658, 1.407)	
p-value of 2-sided stratified log-rank test	0.8458	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	54	55
0	40 (74.1%)	35 (63.6%)
1	6 (11.1%)	10 (18.2%)
2	4 (7.4%)	1 (1.8%)
3	0	3 (5.5%)
>=4	4 (7.4%)	6 (10.9%)
p-value from Interaction Test[c]	0.4967	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	29 (32.2%)	25 (28.7%)
Censored	61 (67.8%)	62 (71.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	4.8 (2.1, 15.4)	6.9 (1.4, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	71.5% (60.5%, 80.0%)	75.1% (64.4%, 83.0%)
Month 12	68.3% (56.9%, 77.3%)	72.0% (60.8%, 80.5%)
Month 18	64.9% (53.0%, 74.5%)	72.0% (60.8%, 80.5%)
Month 24	62.9% (50.7%, 72.9%)	67.0% (54.3%, 76.9%)
Month 30	62.9% (50.7%, 72.9%)	67.0% (54.3%, 76.9%)
Month 36	62.9% (50.7%, 72.9%)	67.0% (54.3%, 76.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.85 (0.499, 1.458)	
p-value of 2-sided stratified log-rank test	0.5646	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	29	25
0	17 (58.6%)	9 (36.0%)
1	3 (10.3%)	5 (20.0%)
2	4 (13.8%)	1 (4.0%)
3	1 (3.4%)	2 (8.0%)
>=4	4 (13.8%)	8 (32.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	4 (11.4%)	7 (21.2%)
Censored	31 (88.6%)	26 (78.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (15.8, NE)	13.9 (0.7, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	91.3% (75.3%, 97.1%)	85.7% (66.0%, 94.4%)
Month 12	91.3% (75.3%, 97.1%)	81.4% (60.6%, 91.9%)
Month 18	87.3% (69.2%, 95.1%)	72.4% (50.1%, 86.0%)
Month 24	87.3% (69.2%, 95.1%)	72.4% (50.1%, 86.0%)
Month 30	87.3% (69.2%, 95.1%)	72.4% (50.1%, 86.0%)
Month 36	87.3% (69.2%, 95.1%)	72.4% (50.1%, 86.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	2.14 (0.602, 7.579)	
p-value of 2-sided stratified log-rank test	0.2337	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	4	7
0	2 (50.0%)	3 (42.9%)
1	0	1 (14.3%)
2	0	1 (14.3%)
3	0	0
>=4	2 (50.0%)	2 (28.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	21 (31.3%)	6 (9.4%)
Censored	46 (68.7%)	58 (90.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.5 (1.4, 22.4)	NE (NE, NE)
50%	NE (22.4, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	71.4% (58.1%, 81.2%)	90.1% (79.3%, 95.4%)
Month 12	66.5% (52.2%, 77.4%)	90.1% (79.3%, 95.4%)
Month 18	66.5% (52.2%, 77.4%)	90.1% (79.3%, 95.4%)
Month 24	62.8% (47.4%, 74.8%)	90.1% (79.3%, 95.4%)
Month 30	62.8% (47.4%, 74.8%)	90.1% (79.3%, 95.4%)
Month 36	58.3% (41.5%, 71.8%)	90.1% (79.3%, 95.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.25 (0.100, 0.614)	
p-value of 2-sided stratified log-rank test	0.0011	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	21	6
0	10 (47.6%)	2 (33.3%)
1	2 (9.5%)	3 (50.0%)
2	4 (19.0%)	0
3	1 (4.8%)	1 (16.7%)
>=4	4 (19.0%)	0
p-value from Interaction Test[c]	0.0125	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	47 (52.2%)	47 (54.0%)
Censored	43 (47.8%)	40 (46.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.0, 3.0)	1.4 (0.8, 2.7)
50%	10.1 (3.5, NE)	10.6 (3.4, 29.3)
75%	NE (NE, NE)	NE (29.3, NE)
Survival probability (95% CI) at		
Month 6	54.8% (43.5%, 64.8%)	53.3% (42.0%, 63.4%)
Month 12	45.5% (34.0%, 56.2%)	46.6% (35.1%, 57.3%)
Month 18	43.7% (32.2%, 54.6%)	42.4% (30.7%, 53.7%)
Month 24	41.5% (29.9%, 52.7%)	39.4% (27.2%, 51.3%)
Month 30	38.3% (26.2%, 50.2%)	35.5% (22.6%, 48.5%)
Month 36	38.3% (26.2%, 50.2%)	35.5% (22.6%, 48.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.90 (0.601, 1.352)	
p-value of 2-sided stratified log-rank test	0.6287	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	47	47
0	29 (61.7%)	25 (53.2%)
1	9 (19.1%)	10 (21.3%)
2	3 (6.4%)	5 (10.6%)
3	1 (2.1%)	1 (2.1%)
>=4	5 (10.6%)	6 (12.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	23 (65.7%)	14 (42.4%)
Censored	12 (34.3%)	19 (57.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 2.5)	2.3 (0.7, 4.2)
50%	2.9 (2.0, 14.3)	NE (3.2, NE)
75%	NE (7.7, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	44.9% (28.0%, 60.4%)	53.9% (33.9%, 70.2%)
Month 12	34.5% (18.9%, 50.7%)	50.0% (30.4%, 66.8%)
Month 18	31.1% (16.2%, 47.3%)	50.0% (30.4%, 66.8%)
Month 24	31.1% (16.2%, 47.3%)	50.0% (30.4%, 66.8%)
Month 30	31.1% (16.2%, 47.3%)	50.0% (30.4%, 66.8%)
Month 36	31.1% (16.2%, 47.3%)	50.0% (30.4%, 66.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.56 (0.790, 3.088)	
p-value of 2-sided stratified log-rank test	0.1925	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	23	14
0	14 (60.9%)	10 (71.4%)
1	6 (26.1%)	2 (14.3%)
2	2 (8.7%)	1 (7.1%)
3	0	0
>=4	1 (4.3%)	1 (7.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	30 (44.8%)	35 (54.7%)
Censored	37 (55.2%)	29 (45.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.3 (0.9, 4.3)	1.5 (0.9, 2.1)
50%	24.2 (4.3, NE)	4.1 (2.1, NE)
75%	41.7 (NE, NE)	NE (12.7, NE)
Survival probability (95% CI) at		
Month 6	57.6% (43.9%, 69.1%)	46.1% (33.0%, 58.2%)
Month 12	55.4% (41.6%, 67.2%)	43.8% (30.7%, 56.1%)
Month 18	52.3% (38.0%, 64.8%)	37.9% (24.7%, 51.1%)
Month 24	52.3% (38.0%, 64.8%)	37.9% (24.7%, 51.1%)
Month 30	45.1% (29.9%, 59.1%)	37.9% (24.7%, 51.1%)
Month 36	45.1% (29.9%, 59.1%)	37.9% (24.7%, 51.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.73 (0.445, 1.185)	
p-value of 2-sided stratified log-rank test	0.2054	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	30	35
0	18 (60.0%)	26 (74.3%)
1	3 (10.0%)	4 (11.4%)
2	4 (13.3%)	1 (2.9%)
3	2 (6.7%)	1 (2.9%)
>=4	3 (10.0%)	3 (8.6%)
p-value from Interaction Test[c]	0.1718	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	66 (73.3%)	72 (82.8%)
Censored	24 (26.7%)	15 (17.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.2 (1.0, 2.8)	1.4 (0.8, 2.8)
50%	9.7 (3.5, 17.4)	7.3 (3.4, 12.9)
75%	26.9 (19.4, 36.2)	19.9 (16.2, 27.0)
Survival probability (95% CI) at		
Month 6	54.0% (42.9%, 63.8%)	52.3% (41.3%, 62.2%)
Month 12	43.1% (32.2%, 53.5%)	40.9% (30.3%, 51.2%)
Month 18	39.0% (28.3%, 49.5%)	28.7% (19.2%, 38.9%)
Month 24	30.3% (20.4%, 40.8%)	19.1% (11.2%, 28.6%)
Month 30	22.7% (13.9%, 32.9%)	13.2% (6.7%, 22.0%)
Month 36	17.4% (9.4%, 27.3%)	13.2% (6.7%, 22.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.80 (0.575, 1.127)	
p-value of 2-sided stratified log-rank test	0.2128	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	66	72
0	48 (72.7%)	50 (69.4%)
1	9 (13.6%)	10 (13.9%)
2	3 (4.5%)	5 (6.9%)
3	1 (1.5%)	1 (1.4%)
>=4	5 (7.6%)	6 (8.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	27 (77.1%)	21 (63.6%)
Censored	8 (22.9%)	12 (36.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 2.5)	2.3 (0.7, 3.8)
50%	2.9 (2.0, 11.3)	4.6 (3.2, 36.1)
75%	22.4 (7.7, NE)	39.1 (9.3, NE)
Survival probability (95% CI) at		
Month 6	44.9% (28.0%, 60.4%)	48.5% (29.6%, 65.0%)
Month 12	32.9% (18.0%, 48.6%)	41.5% (23.8%, 58.4%)
Month 18	26.9% (13.5%, 42.4%)	38.1% (21.0%, 55.1%)
Month 24	23.9% (11.3%, 39.1%)	38.1% (21.0%, 55.1%)
Month 30	23.9% (11.3%, 39.1%)	38.1% (21.0%, 55.1%)
Month 36	20.5% (8.9%, 35.5%)	32.6% (15.9%, 50.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.27 (0.710, 2.270)	
p-value of 2-sided stratified log-rank test	0.4153	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	27	21
0	18 (66.7%)	17 (81.0%)
1	6 (22.2%)	2 (9.5%)
2	2 (7.4%)	1 (4.8%)
3	0	0
>=4	1 (3.7%)	1 (4.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	49 (73.1%)	56 (87.5%)
Censored	18 (26.9%)	8 (12.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.2 (0.9, 2.8)	1.5 (0.8, 2.1)
50%	6.1 (3.6, 13.2)	4.1 (2.1, 9.4)
75%	25.8 (13.4, NE)	15.0 (10.3, 25.8)
Survival probability (95% CI) at		
Month 6	51.3% (38.4%, 62.7%)	43.8% (31.4%, 55.4%)
Month 12	41.4% (29.2%, 53.2%)	32.5% (21.4%, 44.0%)
Month 18	32.6% (21.3%, 44.4%)	21.1% (12.0%, 31.9%)
Month 24	30.8% (19.7%, 42.6%)	17.4% (9.1%, 27.9%)
Month 30	21.2% (11.7%, 32.5%)	11.6% (4.9%, 21.4%)
Month 36	21.2% (11.7%, 32.5%)	9.7% (3.7%, 19.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.73 (0.497, 1.073)	
p-value of 2-sided stratified log-rank test	0.1114	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	49	56
0	37 (75.5%)	47 (83.9%)
1	3 (6.1%)	4 (7.1%)
2	4 (8.2%)	1 (1.8%)
3	2 (4.1%)	1 (1.8%)
>=4	3 (6.1%)	3 (5.4%)
p-value from Interaction Test[c]	0.1960	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	50 (55.6%)	48 (55.2%)
Censored	40 (44.4%)	39 (44.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.0 (0.8, 1.5)
50%	4.2 (1.7, NE)	5.6 (2.8, 31.8)
75%	NE (NE, NE)	NE (31.8, NE)
Survival probability (95% CI) at		
Month 6	46.7% (35.8%, 56.9%)	47.3% (35.9%, 57.8%)
Month 12	40.8% (30.1%, 51.3%)	40.8% (29.5%, 51.7%)
Month 18	40.8% (30.1%, 51.3%)	40.8% (29.5%, 51.7%)
Month 24	40.8% (30.1%, 51.3%)	40.8% (29.5%, 51.7%)
Month 30	40.8% (30.1%, 51.3%)	40.8% (29.5%, 51.7%)
Month 36	40.8% (30.1%, 51.3%)	36.2% (23.5%, 49.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.95 (0.638, 1.410)	
p-value of 2-sided stratified log-rank test	0.8063	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	50	48
0	19 (38.0%)	23 (47.9%)
1	9 (18.0%)	7 (14.6%)
2	5 (10.0%)	6 (12.5%)
3	5 (10.0%)	4 (8.3%)
>=4	12 (24.0%)	8 (16.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	19 (54.3%)	18 (54.5%)
Censored	16 (45.7%)	15 (45.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.2 (0.7, 3.7)	0.8 (0.7, 2.1)
50%	7.1 (2.8, NE)	6.0 (0.9, NE)
75%	NE (28.3, NE)	NE (6.9, NE)
Survival probability (95% CI) at		
Month 6	52.3% (34.2%, 67.5%)	51.5% (32.0%, 67.9%)
Month 12	45.7% (28.2%, 61.6%)	39.2% (21.2%, 56.9%)
Month 18	45.7% (28.2%, 61.6%)	34.8% (17.6%, 52.8%)
Month 24	45.7% (28.2%, 61.6%)	34.8% (17.6%, 52.8%)
Month 30	38.1% (19.1%, 56.9%)	34.8% (17.6%, 52.8%)
Month 36	38.1% (19.1%, 56.9%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.33 (0.688, 2.556)	
p-value of 2-sided stratified log-rank test	0.4198	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	19	18
0	8 (42.1%)	5 (27.8%)
1	6 (31.6%)	4 (22.2%)
2	1 (5.3%)	4 (22.2%)
3	0	2 (11.1%)
>=4	4 (21.1%)	3 (16.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	35 (52.2%)	33 (51.6%)
Censored	32 (47.8%)	31 (48.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.5)	0.9 (0.7, 1.6)
50%	3.7 (1.7, NE)	8.2 (2.1, NE)
75%	NE (33.4, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	45.1% (32.2%, 57.2%)	55.7% (42.4%, 67.2%)
Month 12	42.9% (30.0%, 55.1%)	45.7% (32.4%, 58.0%)
Month 18	42.9% (30.0%, 55.1%)	45.7% (32.4%, 58.0%)
Month 24	42.9% (30.0%, 55.1%)	45.7% (32.4%, 58.0%)
Month 30	42.9% (30.0%, 55.1%)	41.5% (27.4%, 55.1%)
Month 36	34.3% (17.3%, 52.1%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.94 (0.579, 1.511)	
p-value of 2-sided stratified log-rank test	0.7692	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	35	33
0	11 (31.4%)	13 (39.4%)
1	5 (14.3%)	3 (9.1%)
2	3 (8.6%)	3 (9.1%)
3	1 (2.9%)	1 (3.0%)
>=4	15 (42.9%)	13 (39.4%)
p-value from Interaction Test[c]	0.6564	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	52 (57.8%)	60 (69.0%)
Censored	38 (42.2%)	27 (31.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.2)	2.1 (1.4, 2.8)
50%	8.3 (2.9, 21.3)	8.3 (3.5, 11.7)
75%	NE (23.1, NE)	27.2 (14.1, 38.2)
Survival probability (95% CI) at		
Month 6	53.8% (42.7%, 63.6%)	55.3% (43.9%, 65.3%)
Month 12	48.0% (36.9%, 58.3%)	38.5% (27.4%, 49.5%)
Month 18	44.8% (33.7%, 55.4%)	27.8% (17.6%, 39.0%)
Month 24	32.4% (21.2%, 44.0%)	25.7% (15.7%, 36.9%)
Month 30	32.4% (21.2%, 44.0%)	19.0% (10.0%, 30.3%)
Month 36	32.4% (21.2%, 44.0%)	15.9% (7.3%, 27.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.83 (0.570, 1.202)	
p-value of 2-sided stratified log-rank test	0.3161	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	52	60
0	28 (53.8%)	38 (63.3%)
1	12 (23.1%)	9 (15.0%)
2	6 (11.5%)	5 (8.3%)
3	3 (5.8%)	4 (6.7%)
>=4	3 (5.8%)	4 (6.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	24 (68.6%)	18 (54.5%)
Censored	11 (31.4%)	15 (45.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 3.5)	1.4 (0.8, 2.8)
50%	5.6 (1.6, 9.7)	10.9 (1.5, NE)
75%	37.5 (7.1, NE)	NE (28.5, NE)
Survival probability (95% CI) at		
Month 6	49.6% (31.9%, 65.1%)	51.6% (32.3%, 67.8%)
Month 12	33.8% (18.4%, 49.9%)	47.9% (29.0%, 64.5%)
Month 18	33.8% (18.4%, 49.9%)	47.9% (29.0%, 64.5%)
Month 24	29.6% (14.8%, 46.0%)	47.9% (29.0%, 64.5%)
Month 30	29.6% (14.8%, 46.0%)	40.2% (22.3%, 57.5%)
Month 36	29.6% (14.8%, 46.0%)	35.7% (18.5%, 53.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.24 (0.663, 2.311)	
p-value of 2-sided stratified log-rank test	0.4962	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	24	18
0	13 (54.2%)	9 (50.0%)
1	5 (20.8%)	4 (22.2%)
2	3 (12.5%)	2 (11.1%)
3	2 (8.3%)	1 (5.6%)
>=4	1 (4.2%)	2 (11.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	38 (56.7%)	37 (57.8%)
Censored	29 (43.3%)	27 (42.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.9, 4.2)	1.4 (0.8, 2.4)
50%	7.4 (4.2, 15.4)	8.7 (2.8, 17.5)
75%	NE (12.5, NE)	NE (17.5, NE)
Survival probability (95% CI) at		
Month 6	52.1% (38.5%, 64.1%)	50.1% (36.8%, 62.0%)
Month 12	39.9% (26.3%, 53.1%)	41.5% (28.4%, 54.1%)
Month 18	34.7% (21.6%, 48.2%)	36.2% (23.3%, 49.3%)
Month 24	29.4% (16.9%, 43.0%)	36.2% (23.3%, 49.3%)
Month 30	26.5% (14.4%, 40.2%)	36.2% (23.3%, 49.3%)
Month 36	26.5% (14.4%, 40.2%)	30.2% (15.9%, 45.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.00 (0.638, 1.581)	
p-value of 2-sided stratified log-rank test	0.9900	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	38	37
0	26 (68.4%)	20 (54.1%)
1	4 (10.5%)	6 (16.2%)
2	1 (2.6%)	3 (8.1%)
3	3 (7.9%)	2 (5.4%)
>=4	4 (10.5%)	6 (16.2%)
p-value from Interaction Test[c]	0.3891	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	69 (76.7%)	77 (88.5%)
Censored	21 (23.3%)	10 (11.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.2)	2.1 (1.4, 3.0)
50%	7.0 (2.9, 14.0)	7.3 (3.5, 10.0)
75%	28.0 (20.5, NE)	16.7 (12.0, 25.0)
Survival probability (95% CI) at		
Month 6	53.6% (42.6%, 63.3%)	53.5% (42.4%, 63.3%)
Month 12	41.3% (30.9%, 51.5%)	34.5% (24.6%, 44.6%)
Month 18	38.8% (28.4%, 49.0%)	22.6% (14.4%, 32.0%)
Month 24	26.7% (17.6%, 36.7%)	16.4% (9.4%, 25.1%)
Month 30	21.4% (13.1%, 31.0%)	11.2% (5.5%, 19.1%)
Month 36	16.2% (8.7%, 25.6%)	9.3% (4.1%, 17.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.83 (0.597, 1.149)	
p-value of 2-sided stratified log-rank test	0.2557	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	69	77
0	45 (65.2%)	55 (71.4%)
1	12 (17.4%)	9 (11.7%)
2	6 (8.7%)	5 (6.5%)
3	3 (4.3%)	4 (5.2%)
>=4	3 (4.3%)	4 (5.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	25 (71.4%)	21 (63.6%)
Censored	10 (28.6%)	12 (36.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 3.5)	1.4 (0.8, 2.8)
50%	5.6 (1.6, 16.5)	4.6 (1.5, 31.7)
75%	37.5 (7.1, NE)	39.1 (25.1, NE)
Survival probability (95% CI) at		
Month 6	49.6% (31.9%, 65.1%)	48.3% (29.5%, 64.8%)
Month 12	34.1% (18.8%, 50.1%)	44.9% (26.6%, 61.6%)
Month 18	30.7% (16.0%, 46.7%)	44.9% (26.6%, 61.6%)
Month 24	26.9% (12.9%, 43.0%)	44.9% (26.6%, 61.6%)
Month 30	26.9% (12.9%, 43.0%)	38.0% (20.9%, 54.9%)
Month 36	26.9% (12.9%, 43.0%)	30.4% (14.9%, 47.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.13 (0.626, 2.044)	
p-value of 2-sided stratified log-rank test	0.6767	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	25	21
0	14 (56.0%)	12 (57.1%)
1	5 (20.0%)	4 (19.0%)
2	3 (12.0%)	2 (9.5%)
3	2 (8.0%)	1 (4.8%)
>=4	1 (4.0%)	2 (9.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	53 (79.1%)	54 (84.4%)
Censored	14 (20.9%)	10 (15.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.9, 2.8)	1.4 (0.8, 2.4)
50%	5.2 (3.5, 8.4)	5.1 (2.8, 11.0)
75%	15.4 (9.5, 34.0)	17.5 (11.2, 32.2)
Survival probability (95% CI) at		
Month 6	46.6% (34.0%, 58.2%)	46.9% (34.3%, 58.4%)
Month 12	29.4% (18.6%, 41.1%)	33.9% (22.6%, 45.6%)
Month 18	24.2% (14.3%, 35.6%)	24.2% (14.5%, 35.3%)
Month 24	19.0% (10.3%, 29.9%)	20.6% (11.6%, 31.5%)
Month 30	15.6% (7.7%, 25.9%)	16.5% (8.3%, 27.1%)
Month 36	13.3% (6.1%, 23.6%)	11.8% (4.8%, 22.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.00 (0.681, 1.458)	
p-value of 2-sided stratified log-rank test	0.9797	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	53	54
0	41 (77.4%)	37 (68.5%)
1	4 (7.5%)	6 (11.1%)
2	1 (1.9%)	3 (5.6%)
3	3 (5.7%)	2 (3.7%)
>=4	4 (7.5%)	6 (11.1%)
p-value from Interaction Test[c]	0.4540	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	29 (32.2%)	30 (34.5%)
Censored	61 (67.8%)	57 (65.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.0, 19.9)	2.1 (0.8, 13.2)
50%	NE (NE, NE)	NE (27.4, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	70.8% (59.9%, 79.3%)	67.8% (56.7%, 76.7%)
Month 12	66.4% (55.0%, 75.5%)	66.4% (55.1%, 75.5%)
Month 18	66.4% (55.0%, 75.5%)	64.5% (52.9%, 74.0%)
Month 24	64.4% (52.7%, 74.0%)	64.5% (52.9%, 74.0%)
Month 30	64.4% (52.7%, 74.0%)	61.5% (48.8%, 71.9%)
Month 36	64.4% (52.7%, 74.0%)	61.5% (48.8%, 71.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.08 (0.648, 1.801)	
p-value of 2-sided stratified log-rank test	0.7706	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	29	30
0	7 (24.1%)	12 (40.0%)
1	6 (20.7%)	3 (10.0%)
2	0	5 (16.7%)
3	3 (10.3%)	1 (3.3%)
>=4	13 (44.8%)	9 (30.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	13 (37.1%)	11 (33.3%)
Censored	22 (62.9%)	22 (66.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.8 (0.8, NE)	1.4 (0.7, NE)
50%	NE (2.3, NE)	NE (1.4, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	61.7% (43.3%, 75.7%)	66.0% (46.0%, 80.1%)
Month 12	61.7% (43.3%, 75.7%)	66.0% (46.0%, 80.1%)
Month 18	61.7% (43.3%, 75.7%)	61.3% (40.6%, 76.6%)
Month 24	61.7% (43.3%, 75.7%)	61.3% (40.6%, 76.6%)
Month 30	61.7% (43.3%, 75.7%)	61.3% (40.6%, 76.6%)
Month 36	61.7% (43.3%, 75.7%)	61.3% (40.6%, 76.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.06 (0.465, 2.420)	
p-value of 2-sided stratified log-rank test	0.9015	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	13	11
0	5 (38.5%)	8 (72.7%)
1	0	0
2	2 (15.4%)	0
3	2 (15.4%)	1 (9.1%)
>=4	4 (30.8%)	2 (18.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	28 (41.8%)	20 (31.3%)
Censored	39 (58.2%)	44 (68.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.1)	2.8 (0.9, NE)
50%	22.0 (2.8, NE)	NE (13.7, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	58.7% (45.2%, 69.9%)	72.0% (58.8%, 81.6%)
Month 12	54.4% (40.7%, 66.2%)	70.0% (56.7%, 80.0%)
Month 18	54.4% (40.7%, 66.2%)	64.5% (50.0%, 75.8%)
Month 24	49.9% (34.7%, 63.3%)	64.5% (50.0%, 75.8%)
Month 30	49.9% (34.7%, 63.3%)	64.5% (50.0%, 75.8%)
Month 36	49.9% (34.7%, 63.3%)	64.5% (50.0%, 75.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.63 (0.354, 1.120)	
p-value of 2-sided stratified log-rank test	0.1100	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	28	20
0	11 (39.3%)	8 (40.0%)
1	2 (7.1%)	1 (5.0%)
2	6 (21.4%)	1 (5.0%)
3	2 (7.1%)	1 (5.0%)
>=4	7 (25.0%)	9 (45.0%)
p-value from Interaction Test[c]	0.4093	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	63 (70.0%)	52 (59.8%)
Censored	27 (30.0%)	35 (40.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.8, 1.0)	1.4 (0.8, 1.5)
50%	1.6 (1.4, 5.6)	4.3 (2.1, 10.0)
75%	23.1 (11.0, NE)	42.0 (16.7, NE)
Survival probability (95% CI) at		
Month 6	39.3% (29.1%, 49.4%)	47.1% (35.9%, 57.4%)
Month 12	33.6% (23.7%, 43.8%)	39.0% (28.0%, 49.9%)
Month 18	28.9% (19.4%, 39.2%)	34.6% (23.6%, 46.0%)
Month 24	24.9% (15.6%, 35.4%)	34.6% (23.6%, 46.0%)
Month 30	24.9% (15.6%, 35.4%)	34.6% (23.6%, 46.0%)
Month 36	22.2% (12.8%, 33.1%)	34.6% (23.6%, 46.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.33 (0.920, 1.932)	
p-value of 2-sided stratified log-rank test	0.1300	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	63	52
0	40 (63.5%)	27 (51.9%)
1	7 (11.1%)	6 (11.5%)
2	8 (12.7%)	10 (19.2%)
3	3 (4.8%)	4 (7.7%)
>=4	5 (7.9%)	5 (9.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	26 (74.3%)	20 (60.6%)
Censored	9 (25.7%)	13 (39.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.4)	0.9 (0.7, 1.4)
50%	2.2 (1.3, 4.2)	4.4 (1.0, 31.3)
75%	35.7 (3.7, NE)	NE (11.1, NE)
Survival probability (95% CI) at		
Month 6	29.7% (15.6%, 45.3%)	49.5% (30.7%, 65.8%)
Month 12	26.4% (13.0%, 41.9%)	41.6% (23.5%, 58.7%)
Month 18	26.4% (13.0%, 41.9%)	37.4% (20.0%, 54.9%)
Month 24	26.4% (13.0%, 41.9%)	33.2% (16.6%, 50.9%)
Month 30	26.4% (13.0%, 41.9%)	33.2% (16.6%, 50.9%)
Month 36	0 (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.12 (0.614, 2.038)	
p-value of 2-sided stratified log-rank test	0.7007	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	26	20
0	18 (69.2%)	12 (60.0%)
1	1 (3.8%)	3 (15.0%)
2	3 (11.5%)	2 (10.0%)
3	2 (7.7%)	0
>=4	2 (7.7%)	3 (15.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	42 (62.7%)	39 (60.9%)
Censored	25 (37.3%)	25 (39.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.1)	0.9 (0.7, 1.5)
50%	4.4 (2.1, 16.7)	3.4 (1.6, 15.9)
75%	22.4 (16.7, NE)	NE (15.9, NE)
Survival probability (95% CI) at		
Month 6	44.2% (31.2%, 56.5%)	47.8% (34.9%, 59.6%)
Month 12	37.9% (25.3%, 50.5%)	43.8% (31.0%, 55.9%)
Month 18	35.4% (22.9%, 48.1%)	32.5% (19.7%, 45.9%)
Month 24	24.0% (12.6%, 37.3%)	32.5% (19.7%, 45.9%)
Month 30	24.0% (12.6%, 37.3%)	32.5% (19.7%, 45.9%)
Month 36	24.0% (12.6%, 37.3%)	27.0% (13.7%, 42.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.05 (0.678, 1.634)	
p-value of 2-sided stratified log-rank test	0.8177	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	42	39
0	18 (42.9%)	20 (51.3%)
1	12 (28.6%)	8 (20.5%)
2	5 (11.9%)	2 (5.1%)
3	3 (7.1%)	4 (10.3%)
>=4	4 (9.5%)	5 (12.8%)
p-value from Interaction Test[c]	0.7548	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	78 (86.7%)	77 (88.5%)
Censored	12 (13.3%)	10 (11.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.8, 1.1)	1.4 (0.8, 1.6)
50%	2.2 (1.4, 5.6)	5.6 (2.5, 9.8)
75%	15.2 (7.9, 26.5)	16.7 (12.6, 22.2)
Survival probability (95% CI) at		
Month 6	37.7% (27.7%, 47.7%)	47.7% (36.8%, 57.7%)
Month 12	29.2% (20.0%, 39.0%)	35.8% (25.8%, 45.9%)
Month 18	23.1% (14.8%, 32.5%)	22.7% (14.4%, 32.0%)
Month 24	18.3% (10.9%, 27.2%)	14.3% (7.9%, 22.6%)
Month 30	13.4% (7.2%, 21.6%)	13.1% (7.0%, 21.2%)
Month 36	10.3% (4.8%, 18.3%)	11.2% (5.4%, 19.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.11 (0.811, 1.532)	
p-value of 2-sided stratified log-rank test	0.5206	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	78	77
0	55 (70.5%)	52 (67.5%)
1	7 (9.0%)	6 (7.8%)
2	8 (10.3%)	10 (13.0%)
3	3 (3.8%)	4 (5.2%)
>=4	5 (6.4%)	5 (6.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	29 (82.9%)	24 (72.7%)
Censored	6 (17.1%)	9 (27.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.4)	0.9 (0.7, 1.4)
50%	2.2 (1.3, 4.2)	4.1 (1.0, 12.6)
75%	13.2 (3.7, NE)	31.3 (11.1, NE)
Survival probability (95% CI) at		
Month 6	29.7% (15.6%, 45.3%)	46.4% (28.1%, 62.9%)
Month 12	26.7% (13.4%, 42.1%)	39.3% (22.0%, 56.2%)
Month 18	23.4% (10.9%, 38.7%)	32.1% (16.4%, 49.1%)
Month 24	23.4% (10.9%, 38.7%)	28.6% (13.7%, 45.4%)
Month 30	20.1% (8.5%, 35.1%)	28.6% (13.7%, 45.4%)
Month 36	0 (NE, NE)	20.4% (7.9%, 37.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.17 (0.672, 2.052)	
p-value of 2-sided stratified log-rank test	0.5593	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	29	24
0	21 (72.4%)	16 (66.7%)
1	1 (3.4%)	3 (12.5%)
2	3 (10.3%)	2 (8.3%)
3	2 (6.9%)	0
>=4	2 (6.9%)	3 (12.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	51 (76.1%)	59 (92.2%)
Censored	16 (23.9%)	5 (7.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.2 (0.8, 2.1)	0.9 (0.7, 1.5)
50%	3.0 (2.1, 6.1)	3.5 (1.6, 10.2)
75%	18.9 (7.4, NE)	15.9 (10.3, 28.2)
Survival probability (95% CI) at		
Month 6	38.4% (26.5%, 50.2%)	46.9% (34.3%, 58.4%)
Month 12	31.5% (20.4%, 43.2%)	34.4% (23.1%, 45.9%)
Month 18	27.6% (16.9%, 39.2%)	20.3% (11.5%, 30.9%)
Month 24	19.3% (10.2%, 30.7%)	17.2% (9.2%, 27.3%)
Month 30	17.2% (8.5%, 28.4%)	13.9% (6.8%, 23.5%)
Month 36	17.2% (8.5%, 28.4%)	4.3% (0.5%, 15.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.89 (0.609, 1.298)	
p-value of 2-sided stratified log-rank test	0.5369	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	51	59
0	27 (52.9%)	40 (67.8%)
1	12 (23.5%)	8 (13.6%)
2	5 (9.8%)	2 (3.4%)
3	3 (5.9%)	4 (6.8%)
>=4	4 (7.8%)	5 (8.5%)
p-value from Interaction Test[c]	0.4849	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	23 (25.6%)	19 (21.8%)
Censored	67 (74.4%)	68 (78.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	5.6 (2.6, NE)	NE (2.8, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	73.9% (63.1%, 82.0%)	80.7% (70.4%, 87.7%)
Month 12	73.9% (63.1%, 82.0%)	77.3% (66.2%, 85.2%)
Month 18	72.0% (60.7%, 80.6%)	75.2% (63.6%, 83.6%)
Month 24	72.0% (60.7%, 80.6%)	75.2% (63.6%, 83.6%)
Month 30	72.0% (60.7%, 80.6%)	75.2% (63.6%, 83.6%)
Month 36	72.0% (60.7%, 80.6%)	75.2% (63.6%, 83.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.84 (0.459, 1.549)	
p-value of 2-sided stratified log-rank test	0.5753	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	23	19
0	9 (39.1%)	13 (68.4%)
1	3 (13.0%)	1 (5.3%)
2	1 (4.3%)	1 (5.3%)
3	3 (13.0%)	1 (5.3%)
>=4	7 (30.4%)	3 (15.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	8 (22.9%)	14 (42.4%)
Censored	27 (77.1%)	19 (57.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (2.1, NE)	1.6 (0.7, 3.5)
50%	NE (NE, NE)	NE (2.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	76.5% (58.4%, 87.5%)	58.9% (39.1%, 74.2%)
Month 12	76.5% (58.4%, 87.5%)	55.3% (35.6%, 71.1%)
Month 18	76.5% (58.4%, 87.5%)	51.3% (31.9%, 67.7%)
Month 24	76.5% (58.4%, 87.5%)	51.3% (31.9%, 67.7%)
Month 30	76.5% (58.4%, 87.5%)	51.3% (31.9%, 67.7%)
Month 36	76.5% (58.4%, 87.5%)	51.3% (31.9%, 67.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	2.42 (1.002, 5.849)	
p-value of 2-sided stratified log-rank test	0.0409	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	8	14
0	4 (50.0%)	3 (21.4%)
1	1 (12.5%)	1 (7.1%)
2	1 (12.5%)	5 (35.7%)
3	1 (12.5%)	0
>=4	1 (12.5%)	5 (35.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	18 (26.9%)	15 (23.4%)
Censored	49 (73.1%)	49 (76.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.9 (1.4, NE)	9.8 (2.1, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	73.8% (60.8%, 83.0%)	76.7% (63.8%, 85.5%)
Month 12	68.9% (55.0%, 79.4%)	74.3% (60.8%, 83.7%)
Month 18	68.9% (55.0%, 79.4%)	74.3% (60.8%, 83.7%)
Month 24	68.9% (55.0%, 79.4%)	74.3% (60.8%, 83.7%)
Month 30	68.9% (55.0%, 79.4%)	74.3% (60.8%, 83.7%)
Month 36	68.9% (55.0%, 79.4%)	74.3% (60.8%, 83.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.80 (0.403, 1.592)	
p-value of 2-sided stratified log-rank test	0.5282	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	18	15
0	9 (50.0%)	6 (40.0%)
1	2 (11.1%)	0
2	2 (11.1%)	3 (20.0%)
3	0	1 (6.7%)
>=4	5 (27.8%)	5 (33.3%)
p-value from Interaction Test[c]	0.1125	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	60 (66.7%)	51 (58.6%)
Censored	30 (33.3%)	36 (41.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.1)	2.5 (1.4, 4.2)
50%	4.2 (2.8, 8.1)	7.9 (5.0, 11.8)
75%	31.9 (21.9, NE)	NE (11.9, NE)
Survival probability (95% CI) at		
Month 6	42.6% (31.9%, 52.8%)	57.6% (46.0%, 67.7%)
Month 12	37.0% (26.7%, 47.4%)	35.5% (24.0%, 47.1%)
Month 18	35.6% (25.3%, 46.0%)	31.4% (20.3%, 43.1%)
Month 24	31.5% (21.2%, 42.3%)	31.4% (20.3%, 43.1%)
Month 30	26.8% (16.6%, 38.0%)	26.6% (15.8%, 38.6%)
Month 36	21.1% (11.3%, 33.0%)	26.6% (15.8%, 38.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.28 (0.882, 1.866)	
p-value of 2-sided stratified log-rank test	0.1952	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	60	51
0	40 (66.7%)	32 (62.7%)
1	9 (15.0%)	10 (19.6%)
2	6 (10.0%)	4 (7.8%)
3	1 (1.7%)	1 (2.0%)
>=4	4 (6.7%)	4 (7.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	23 (65.7%)	19 (57.6%)
Censored	12 (34.3%)	14 (42.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.2)	2.8 (0.8, 7.4)
50%	2.8 (1.6, 8.8)	19.6 (2.8, 30.2)
75%	NE (3.6, NE)	NE (22.8, NE)
Survival probability (95% CI) at		
Month 6	34.2% (18.8%, 50.2%)	61.8% (41.6%, 76.8%)
Month 12	30.8% (16.1%, 46.8%)	53.6% (33.5%, 70.0%)
Month 18	30.8% (16.1%, 46.8%)	53.6% (33.5%, 70.0%)
Month 24	30.8% (16.1%, 46.8%)	37.1% (19.2%, 55.1%)
Month 30	30.8% (16.1%, 46.8%)	33.0% (16.1%, 51.0%)
Month 36	30.8% (16.1%, 46.8%)	28.8% (13.1%, 46.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.55 (0.822, 2.916)	
p-value of 2-sided stratified log-rank test	0.1775	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	23	19
0	18 (78.3%)	15 (78.9%)
1	3 (13.0%)	0
2	2 (8.7%)	2 (10.5%)
3	0	1 (5.3%)
>=4	0	1 (5.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	31 (46.3%)	30 (46.9%)
Censored	36 (53.7%)	34 (53.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	4.2 (1.4, 7.1)	2.9 (1.4, 8.3)
50%	17.9 (7.1, 25.3)	21.1 (8.3, NE)
75%	NE (19.5, NE)	NE (31.1, NE)
Survival probability (95% CI) at		
Month 6	69.6% (56.1%, 79.7%)	66.2% (52.5%, 76.7%)
Month 12	56.0% (41.3%, 68.4%)	52.7% (38.3%, 65.3%)
Month 18	46.9% (31.6%, 60.8%)	52.7% (38.3%, 65.3%)
Month 24	35.4% (20.2%, 51.1%)	48.7% (33.4%, 62.3%)
Month 30	29.5% (14.2%, 46.7%)	44.2% (28.3%, 59.0%)
Month 36	29.5% (14.2%, 46.7%)	33.2% (16.7%, 50.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.12 (0.676, 1.869)	
p-value of 2-sided stratified log-rank test	0.6515	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	31	30
0	27 (87.1%)	19 (63.3%)
1	3 (9.7%)	6 (20.0%)
2	0	3 (10.0%)
3	0	2 (6.7%)
>=4	1 (3.2%)	0
p-value from Interaction Test[c]	0.7213	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	76 (84.4%)	73 (83.9%)
Censored	14 (15.6%)	14 (16.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.2)	2.8 (1.4, 4.1)
50%	3.8 (2.8, 6.2)	7.6 (5.0, 10.3)
75%	21.9 (9.6, 31.9)	16.3 (11.8, 27.4)
Survival probability (95% CI) at		
Month 6	41.1% (30.8%, 51.1%)	55.4% (44.2%, 65.2%)
Month 12	31.9% (22.4%, 41.7%)	31.4% (21.8%, 41.4%)
Month 18	29.4% (20.2%, 39.1%)	22.7% (14.4%, 32.2%)
Month 24	23.0% (14.7%, 32.4%)	20.1% (12.2%, 29.4%)
Month 30	17.9% (10.5%, 26.8%)	16.1% (9.0%, 24.9%)
Month 36	10.7% (5.0%, 18.8%)	14.1% (7.3%, 23.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.16 (0.841, 1.603)	
p-value of 2-sided stratified log-rank test	0.3662	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	76	73
0	56 (73.7%)	54 (74.0%)
1	9 (11.8%)	10 (13.7%)
2	6 (7.9%)	4 (5.5%)
3	1 (1.3%)	1 (1.4%)
>=4	4 (5.3%)	4 (5.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	26 (74.3%)	23 (69.7%)
Censored	9 (25.7%)	10 (30.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.2)	2.8 (0.8, 3.8)
50%	2.8 (1.6, 8.8)	18.1 (2.8, 25.1)
75%	13.2 (3.6, NE)	34.7 (22.3, NE)
Survival probability (95% CI) at		
Month 6	34.2% (18.8%, 50.2%)	58.8% (38.9%, 74.1%)
Month 12	31.1% (16.4%, 47.0%)	51.4% (32.1%, 67.8%)
Month 18	24.2% (11.1%, 39.9%)	51.4% (32.1%, 67.8%)
Month 24	24.2% (11.1%, 39.9%)	33.1% (16.8%, 50.3%)
Month 30	20.1% (8.2%, 35.8%)	29.4% (14.1%, 46.6%)
Month 36	20.1% (8.2%, 35.8%)	20.6% (7.6%, 37.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.47 (0.820, 2.622)	
p-value of 2-sided stratified log-rank test	0.1998	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	26	23
0	21 (80.8%)	19 (82.6%)
1	3 (11.5%)	0
2	2 (7.7%)	2 (8.7%)
3	0	1 (4.3%)
>=4	0	1 (4.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	52 (77.6%)	53 (82.8%)
Censored	15 (22.4%)	11 (17.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.1, 5.6)	2.7 (1.2, 5.6)
50%	8.3 (6.1, 13.4)	9.9 (5.6, 13.2)
75%	19.5 (13.4, 25.8)	22.0 (13.4, 33.1)
Survival probability (95% CI) at		
Month 6	63.8% (50.7%, 74.3%)	62.5% (49.5%, 73.1%)
Month 12	39.8% (27.5%, 51.8%)	41.2% (28.9%, 53.0%)
Month 18	29.0% (18.0%, 40.9%)	29.6% (18.9%, 41.2%)
Month 24	20.8% (11.3%, 32.4%)	22.2% (12.7%, 33.5%)
Month 30	10.4% (3.9%, 20.5%)	18.2% (9.5%, 29.2%)
Month 36	10.4% (3.9%, 20.5%)	11.8% (4.8%, 22.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.11 (0.755, 1.633)	
p-value of 2-sided stratified log-rank test	0.5972	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	52	53
0	48 (92.3%)	42 (79.2%)
1	3 (5.8%)	6 (11.3%)
2	0	3 (5.7%)
3	0	2 (3.8%)
>=4	1 (1.9%)	0
p-value from Interaction Test[c]	0.6084	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	18 (20.0%)	13 (14.9%)
Censored	72 (80.0%)	74 (85.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (1.6, NE)	NE (8.3, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	80.1% (69.9%, 87.2%)	85.8% (76.4%, 91.7%)
Month 12	78.4% (67.7%, 85.9%)	84.3% (74.4%, 90.6%)
Month 18	78.4% (67.7%, 85.9%)	84.3% (74.4%, 90.6%)
Month 24	78.4% (67.7%, 85.9%)	84.3% (74.4%, 90.6%)
Month 30	78.4% (67.7%, 85.9%)	84.3% (74.4%, 90.6%)
Month 36	78.4% (67.7%, 85.9%)	84.3% (74.4%, 90.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.71 (0.350, 1.458)	
p-value of 2-sided stratified log-rank test	0.3543	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	18	13
0	5 (27.8%)	6 (46.2%)
1	3 (16.7%)	1 (7.7%)
2	2 (11.1%)	0
3	2 (11.1%)	3 (23.1%)
>=4	6 (33.3%)	3 (23.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	5 (14.3%)	6 (18.2%)
Censored	30 (85.7%)	27 (81.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (2.3, NE)	NE (0.7, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	85.0% (67.7%, 93.5%)	80.0% (60.8%, 90.5%)
Month 12	85.0% (67.7%, 93.5%)	80.0% (60.8%, 90.5%)
Month 18	85.0% (67.7%, 93.5%)	80.0% (60.8%, 90.5%)
Month 24	85.0% (67.7%, 93.5%)	80.0% (60.8%, 90.5%)
Month 30	85.0% (67.7%, 93.5%)	80.0% (60.8%, 90.5%)
Month 36	85.0% (67.7%, 93.5%)	80.0% (60.8%, 90.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.64 (0.499, 5.360)	
p-value of 2-sided stratified log-rank test	0.4201	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	5	6
0	2 (40.0%)	3 (50.0%)
1	0	1 (16.7%)
2	0	0
3	2 (40.0%)	1 (16.7%)
>=4	1 (20.0%)	1 (16.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	11 (16.4%)	11 (17.2%)
Censored	56 (83.6%)	53 (82.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (1.4, NE)	NE (1.4, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	83.6% (71.7%, 90.8%)	83.7% (71.8%, 90.9%)
Month 12	81.3% (68.6%, 89.2%)	81.4% (68.7%, 89.3%)
Month 18	81.3% (68.6%, 89.2%)	81.4% (68.7%, 89.3%)
Month 24	81.3% (68.6%, 89.2%)	81.4% (68.7%, 89.3%)
Month 30	81.3% (68.6%, 89.2%)	81.4% (68.7%, 89.3%)
Month 36	81.3% (68.6%, 89.2%)	81.4% (68.7%, 89.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.00 (0.434, 2.323)	
p-value of 2-sided stratified log-rank test	0.9964	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	11	11
0	1 (9.1%)	4 (36.4%)
1	5 (45.5%)	1 (9.1%)
2	1 (9.1%)	1 (9.1%)
3	2 (18.2%)	0
>=4	2 (18.2%)	5 (45.5%)
p-value from Interaction Test[c]	0.5694	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	37 (41.1%)	31 (35.6%)
Censored	53 (58.9%)	56 (64.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.4 (1.4, 12.5)	10.4 (3.0, 18.1)
50%	NE (18.0, NE)	29.4 (18.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	70.1% (59.3%, 78.6%)	78.0% (67.3%, 85.6%)
Month 12	67.4% (56.3%, 76.3%)	71.3% (59.5%, 80.3%)
Month 18	62.7% (51.2%, 72.3%)	65.2% (52.2%, 75.4%)
Month 24	51.9% (39.6%, 62.9%)	55.5% (41.4%, 67.5%)
Month 30	51.9% (39.6%, 62.9%)	48.5% (33.4%, 62.1%)
Month 36	51.9% (39.6%, 62.9%)	48.5% (33.4%, 62.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.13 (0.697, 1.817)	
p-value of 2-sided stratified log-rank test	0.6315	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	37	31
0	23 (62.2%)	21 (67.7%)
1	7 (18.9%)	4 (12.9%)
2	2 (5.4%)	4 (12.9%)
3	1 (2.7%)	0
>=4	4 (10.8%)	2 (6.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	14 (40.0%)	9 (27.3%)
Censored	21 (60.0%)	24 (72.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (0.8, 24.0)	5.6 (0.8, NE)
50%	NE (4.4, NE)	NE (7.2, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	65.1% (46.8%, 78.5%)	74.7% (53.8%, 87.1%)
Month 12	61.8% (43.4%, 75.8%)	70.5% (49.3%, 84.2%)
Month 18	61.8% (43.4%, 75.8%)	70.5% (49.3%, 84.2%)
Month 24	57.1% (37.9%, 72.4%)	66.1% (44.5%, 80.9%)
Month 30	57.1% (37.9%, 72.4%)	66.1% (44.5%, 80.9%)
Month 36	57.1% (37.9%, 72.4%)	66.1% (44.5%, 80.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.49 (0.625, 3.559)	
p-value of 2-sided stratified log-rank test	0.3639	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	14	9
0	8 (57.1%)	6 (66.7%)
1	3 (21.4%)	1 (11.1%)
2	3 (21.4%)	1 (11.1%)
3	0	0
>=4	0	1 (11.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	29 (43.3%)	30 (46.9%)
Censored	38 (56.7%)	34 (53.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.4 (1.4, 4.6)	3.5 (1.4, 8.3)
50%	27.9 (4.6, NE)	19.8 (8.3, NE)
75%	NE (NE, NE)	NE (25.2, NE)
Survival probability (95% CI) at		
Month 6	62.6% (48.9%, 73.6%)	66.2% (52.6%, 76.8%)
Month 12	54.5% (40.5%, 66.5%)	56.0% (41.9%, 68.0%)
Month 18	54.5% (40.5%, 66.5%)	50.1% (35.4%, 63.2%)
Month 24	51.0% (36.5%, 63.9%)	43.4% (28.3%, 57.6%)
Month 30	46.8% (31.4%, 60.8%)	39.4% (24.2%, 54.3%)
Month 36	42.1% (26.0%, 57.4%)	39.4% (24.2%, 54.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.98 (0.583, 1.636)	
p-value of 2-sided stratified log-rank test	0.9228	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	29	30
0	19 (65.5%)	18 (60.0%)
1	4 (13.8%)	2 (6.7%)
2	2 (6.9%)	6 (20.0%)
3	1 (3.4%)	0
>=4	3 (10.3%)	4 (13.3%)
p-value from Interaction Test[c]	0.7334	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	59 (65.6%)	65 (74.7%)
Censored	31 (34.4%)	22 (25.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.4 (1.4, 7.0)	6.7 (3.4, 11.2)
50%	19.2 (11.0, 24.3)	17.3 (12.9, 19.0)
75%	NE (26.5, NE)	27.4 (21.2, NE)
Survival probability (95% CI) at		
Month 6	69.5% (58.8%, 78.0%)	75.4% (64.8%, 83.2%)
Month 12	60.1% (49.1%, 69.5%)	64.3% (53.0%, 73.5%)
Month 18	54.0% (42.9%, 63.8%)	46.4% (35.2%, 56.8%)
Month 24	40.2% (29.7%, 50.5%)	29.0% (19.4%, 39.3%)
Month 30	33.7% (23.7%, 44.0%)	21.8% (13.2%, 31.7%)
Month 36	28.8% (19.1%, 39.2%)	19.8% (11.5%, 29.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.83 (0.583, 1.183)	
p-value of 2-sided stratified log-rank test	0.3026	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	59	65
0	45 (76.3%)	55 (84.6%)
1	7 (11.9%)	4 (6.2%)
2	2 (3.4%)	4 (6.2%)
3	1 (1.7%)	0
>=4	4 (6.8%)	2 (3.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	19 (54.3%)	19 (57.6%)
Censored	16 (45.7%)	14 (42.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (0.8, 13.0)	5.3 (0.8, 13.6)
50%	22.4 (4.4, NE)	31.7 (5.6, 36.6)
75%	NE (28.6, NE)	39.1 (34.7, NE)
Survival probability (95% CI) at		
Month 6	65.1% (46.8%, 78.5%)	69.1% (49.0%, 82.6%)
Month 12	62.1% (43.8%, 76.0%)	65.7% (45.6%, 79.9%)
Month 18	55.9% (37.8%, 70.7%)	58.8% (38.9%, 74.1%)
Month 24	45.4% (27.8%, 61.5%)	51.9% (32.6%, 68.0%)
Month 30	41.9% (24.8%, 58.2%)	51.9% (32.6%, 68.0%)
Month 36	41.9% (24.8%, 58.2%)	43.3% (24.6%, 60.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.95 (0.499, 1.814)	
p-value of 2-sided stratified log-rank test	0.8745	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	19	19
0	13 (68.4%)	16 (84.2%)
1	3 (15.8%)	1 (5.3%)
2	3 (15.8%)	1 (5.3%)
3	0	0
>=4	0	1 (5.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	47 (70.1%)	55 (85.9%)
Censored	20 (29.9%)	9 (14.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.3 (1.4, 3.6)	2.7 (1.0, 5.6)
50%	7.1 (4.2, 18.0)	9.9 (5.8, 15.3)
75%	27.9 (18.0, NE)	22.0 (15.9, 28.2)
Survival probability (95% CI) at		
Month 6	55.8% (42.7%, 67.0%)	62.5% (49.5%, 73.1%)
Month 12	45.7% (33.0%, 57.5%)	43.8% (31.4%, 55.4%)
Month 18	38.4% (26.2%, 50.4%)	29.7% (19.1%, 41.1%)
Month 24	30.6% (19.2%, 42.7%)	23.2% (13.8%, 34.2%)
Month 30	24.3% (13.9%, 36.3%)	14.9% (7.4%, 24.9%)
Month 36	21.9% (11.9%, 33.8%)	13.3% (6.3%, 22.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.92 (0.621, 1.363)	
p-value of 2-sided stratified log-rank test	0.6710	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	47	55
0	37 (78.7%)	43 (78.2%)
1	4 (8.5%)	2 (3.6%)
2	2 (4.3%)	6 (10.9%)
3	1 (2.1%)	0
>=4	3 (6.4%)	4 (7.3%)
p-value from Interaction Test[c]	0.9421	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	25 (27.8%)	18 (20.7%)
Censored	65 (72.2%)	69 (79.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	4.1 (2.0, NE)	NE (3.5, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	74.4% (63.8%, 82.4%)	82.1% (72.1%, 88.8%)
Month 12	72.8% (61.9%, 81.1%)	82.1% (72.1%, 88.8%)
Month 18	71.1% (59.8%, 79.7%)	80.1% (69.3%, 87.4%)
Month 24	68.8% (57.0%, 78.0%)	75.2% (62.6%, 84.1%)
Month 30	68.8% (57.0%, 78.0%)	75.2% (62.6%, 84.1%)
Month 36	68.8% (57.0%, 78.0%)	75.2% (62.6%, 84.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.72 (0.391, 1.314)	
p-value of 2-sided stratified log-rank test	0.2787	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	25	18
0	11 (44.0%)	7 (38.9%)
1	2 (8.0%)	1 (5.6%)
2	4 (16.0%)	2 (11.1%)
3	1 (4.0%)	2 (11.1%)
>=4	7 (28.0%)	6 (33.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	9 (25.7%)	8 (24.2%)
Censored	26 (74.3%)	25 (75.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	15.8 (0.9, NE)	2.4 (0.7, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	76.4% (58.3%, 87.5%)	72.9% (53.0%, 85.4%)
Month 12	76.4% (58.3%, 87.5%)	72.9% (53.0%, 85.4%)
Month 18	72.2% (52.9%, 84.6%)	72.9% (53.0%, 85.4%)
Month 24	72.2% (52.9%, 84.6%)	72.9% (53.0%, 85.4%)
Month 30	72.2% (52.9%, 84.6%)	72.9% (53.0%, 85.4%)
Month 36	72.2% (52.9%, 84.6%)	72.9% (53.0%, 85.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.21 (0.468, 3.151)	
p-value of 2-sided stratified log-rank test	0.7143	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	9	8
0	2 (22.2%)	2 (25.0%)
1	1 (11.1%)	2 (25.0%)
2	3 (33.3%)	0
3	0	1 (12.5%)
>=4	3 (33.3%)	3 (37.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	14 (20.9%)	15 (23.4%)
Censored	53 (79.1%)	49 (76.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	12.5 (1.5, NE)	21.1 (1.4, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	80.0% (67.4%, 88.1%)	78.7% (66.1%, 87.0%)
Month 12	77.5% (64.1%, 86.4%)	78.7% (66.1%, 87.0%)
Month 18	74.5% (60.1%, 84.3%)	76.1% (62.6%, 85.2%)
Month 24	74.5% (60.1%, 84.3%)	72.4% (57.4%, 82.9%)
Month 30	74.5% (60.1%, 84.3%)	72.4% (57.4%, 82.9%)
Month 36	74.5% (60.1%, 84.3%)	72.4% (57.4%, 82.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.04 (0.504, 2.163)	
p-value of 2-sided stratified log-rank test	0.9130	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	14	15
0	4 (28.6%)	6 (40.0%)
1	3 (21.4%)	2 (13.3%)
2	1 (7.1%)	2 (13.3%)
3	1 (7.1%)	1 (6.7%)
>=4	5 (35.7%)	4 (26.7%)
p-value from Interaction Test[c]	0.6186	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	115 (85.2%)	110 (80.3%)
Censored	20 (14.8%)	27 (19.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 0.9)
50%	1.4 (1.4, 2.1)	1.4 (1.4, 2.3)
75%	3.0 (2.6, 6.5)	6.1 (2.9, 14.3)
Survival probability (95% CI) at		
Month 6	18.4% (12.2%, 25.5%)	25.2% (18.1%, 33.0%)
Month 12	12.8% (7.4%, 19.8%)	19.9% (13.2%, 27.6%)
Month 18	11.6% (6.3%, 18.5%)	13.2% (7.3%, 20.8%)
Month 24	8.7% (4.0%, 15.5%)	11.7% (6.1%, 19.3%)
Month 30	8.7% (4.0%, 15.5%)	8.5% (3.7%, 15.9%)
Month 36	6.5% (2.3%, 13.7%)	8.5% (3.7%, 15.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.10 (0.840, 1.428)	
p-value of 2-sided stratified log-rank test	0.4814	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	115	110
0	37 (32.2%)	43 (39.1%)
1	15 (13.0%)	19 (17.3%)
2	12 (10.4%)	7 (6.4%)
3	12 (10.4%)	8 (7.3%)
>=4	39 (33.9%)	33 (30.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	44 (77.2%)	37 (78.7%)
Censored	13 (22.8%)	10 (21.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 0.9)
50%	1.8 (0.9, 2.3)	1.4 (0.8, 2.4)
75%	3.1 (2.2, NE)	7.1 (2.3, NE)
Survival probability (95% CI) at		
Month 6	20.8% (11.1%, 32.5%)	25.9% (14.1%, 39.5%)
Month 12	17.3% (8.0%, 29.5%)	20.7% (10.1%, 33.9%)
Month 18	13.8% (5.4%, 26.2%)	20.7% (10.1%, 33.9%)
Month 24	13.8% (5.4%, 26.2%)	17.3% (7.4%, 30.6%)
Month 30	13.8% (5.4%, 26.2%)	13.0% (4.2%, 26.7%)
Month 36	NE (NE, NE)	13.0% (4.2%, 26.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.90 (0.566, 1.437)	
p-value of 2-sided stratified log-rank test	0.6874	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	44	37
0	20 (45.5%)	12 (32.4%)
1	9 (20.5%)	5 (13.5%)
2	3 (6.8%)	4 (10.8%)
3	4 (9.1%)	2 (5.4%)
>=4	8 (18.2%)	14 (37.8%)
p-value from Interaction Test[c]	0.7757	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	123 (91.1%)	128 (93.4%)
Censored	12 (8.9%)	9 (6.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 0.9)
50%	1.4 (1.4, 2.1)	1.4 (1.4, 2.4)
75%	3.0 (2.6, 6.5)	6.1 (3.5, 12.0)
Survival probability (95% CI) at		
Month 6	18.4% (12.3%, 25.5%)	25.4% (18.4%, 33.0%)
Month 12	12.2% (7.1%, 18.7%)	17.6% (11.6%, 24.5%)
Month 18	9.4% (5.0%, 15.5%)	8.8% (4.7%, 14.5%)
Month 24	6.6% (3.0%, 12.1%)	7.2% (3.6%, 12.5%)
Month 30	5.6% (2.4%, 10.9%)	4.0% (1.5%, 8.5%)
Month 36	3.4% (1.0%, 8.3%)	2.7% (0.7%, 7.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.07 (0.830, 1.375)	
p-value of 2-sided stratified log-rank test	0.5905	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	123	128
0	45 (36.6%)	61 (47.7%)
1	15 (12.2%)	19 (14.8%)
2	12 (9.8%)	7 (5.5%)
3	12 (9.8%)	8 (6.3%)
>=4	39 (31.7%)	33 (25.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	52 (91.2%)	40 (85.1%)
Censored	5 (8.8%)	7 (14.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.0)	0.8 (0.7, 0.9)
50%	1.9 (1.0, 2.2)	1.4 (0.8, 2.4)
75%	3.4 (2.3, 6.1)	4.9 (2.3, 19.6)
Survival probability (95% CI) at		
Month 6	16.1% (7.9%, 26.8%)	24.4% (13.2%, 37.6%)
Month 12	8.9% (3.3%, 18.1%)	17.8% (8.3%, 30.1%)
Month 18	7.1% (2.3%, 15.8%)	17.8% (8.3%, 30.1%)
Month 24	7.1% (2.3%, 15.8%)	12.7% (4.9%, 24.4%)
Month 30	7.1% (2.3%, 15.8%)	9.5% (2.9%, 21.0%)
Month 36	NE (NE, NE)	9.5% (2.9%, 21.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.04 (0.668, 1.620)	
p-value of 2-sided stratified log-rank test	0.8122	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	52	40
0	28 (53.8%)	15 (37.5%)
1	9 (17.3%)	5 (12.5%)
2	3 (5.8%)	4 (10.0%)
3	4 (7.7%)	2 (5.0%)
>=4	8 (15.4%)	14 (35.0%)
p-value from Interaction Test[c]	0.8720	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	85 (63.0%)	89 (65.0%)
Censored	50 (37.0%)	48 (35.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.8)	1.0 (0.8, 1.4)
50%	6.6 (3.4, 8.5)	5.3 (2.8, 9.7)
75%	NE (18.9, NE)	29.2 (12.3, NE)
Survival probability (95% CI) at		
Month 6	51.1% (42.2%, 59.4%)	44.8% (35.9%, 53.3%)
Month 12	38.1% (29.4%, 46.7%)	34.3% (25.6%, 43.1%)
Month 18	34.6% (25.9%, 43.4%)	27.5% (19.3%, 36.3%)
Month 24	27.5% (19.0%, 36.6%)	26.1% (18.0%, 34.9%)
Month 30	27.5% (19.0%, 36.6%)	24.4% (16.3%, 33.3%)
Month 36	27.5% (19.0%, 36.6%)	24.4% (16.3%, 33.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.07 (0.791, 1.447)	
p-value of 2-sided stratified log-rank test	0.6618	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	85	89
0	48 (56.5%)	41 (46.1%)
1	14 (16.5%)	16 (18.0%)
2	4 (4.7%)	11 (12.4%)
3	4 (4.7%)	3 (3.4%)
>=4	15 (17.6%)	18 (20.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	33 (57.9%)	28 (59.6%)
Censored	24 (42.1%)	19 (40.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.1)	0.9 (0.8, 2.1)
50%	3.4 (1.6, 8.3)	6.1 (2.1, 12.5)
75%	NE (6.2, NE)	NE (11.2, NE)
Survival probability (95% CI) at		
Month 6	44.4% (30.2%, 57.6%)	50.8% (35.5%, 64.3%)
Month 12	29.3% (16.2%, 43.8%)	38.2% (23.8%, 52.4%)
Month 18	29.3% (16.2%, 43.8%)	35.5% (21.4%, 49.8%)
Month 24	29.3% (16.2%, 43.8%)	35.5% (21.4%, 49.8%)
Month 30	29.3% (16.2%, 43.8%)	35.5% (21.4%, 49.8%)
Month 36	NE (NE, NE)	35.5% (21.4%, 49.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Fatigue Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.73 (0.424, 1.249)	
p-value of 2-sided stratified log-rank test	0.2478	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	33	28
0	17 (51.5%)	8 (28.6%)
1	9 (27.3%)	7 (25.0%)
2	2 (6.1%)	7 (25.0%)
3	1 (3.0%)	2 (7.1%)
>=4	4 (12.1%)	4 (14.3%)
p-value from Interaction Test[c]	0.2867	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	92 (68.1%)	86 (62.8%)
Censored	43 (31.9%)	51 (37.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 1.5)	1.4 (0.9, 2.1)
50%	3.5 (2.6, 4.7)	4.4 (3.3, 11.3)
75%	37.7 (18.5, NE)	31.3 (14.8, NE)
Survival probability (95% CI) at		
Month 6	39.5% (31.1%, 47.9%)	48.9% (39.9%, 57.2%)
Month 12	35.8% (27.5%, 44.2%)	39.6% (30.7%, 48.4%)
Month 18	33.6% (25.3%, 42.0%)	32.0% (23.2%, 41.1%)
Month 24	29.9% (21.7%, 38.5%)	28.8% (20.0%, 38.2%)
Month 30	28.5% (20.3%, 37.2%)	27.1% (18.4%, 36.6%)
Month 36	27.0% (18.8%, 35.8%)	22.6% (13.8%, 32.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.04 (0.770, 1.397)	
p-value of 2-sided stratified log-rank test	0.8243	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	92	86
0	63 (68.5%)	62 (72.1%)
1	12 (13.0%)	11 (12.8%)
2	10 (10.9%)	6 (7.0%)
3	5 (5.4%)	3 (3.5%)
>=4	2 (2.2%)	4 (4.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	36 (63.2%)	26 (55.3%)
Censored	21 (36.8%)	21 (44.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.5)	0.9 (0.7, 2.9)
50%	2.8 (1.5, 5.6)	8.7 (2.8, NE)
75%	24.1 (5.6, NE)	NE (24.6, NE)
Survival probability (95% CI) at		
Month 6	36.3% (23.1%, 49.6%)	52.8% (37.2%, 66.2%)
Month 12	36.3% (23.1%, 49.6%)	49.9% (34.2%, 63.7%)
Month 18	33.3% (20.2%, 46.9%)	43.2% (27.5%, 57.9%)
Month 24	29.1% (16.0%, 43.5%)	43.2% (27.5%, 57.9%)
Month 30	20.8% (8.9%, 36.0%)	39.3% (23.6%, 54.6%)
Month 36	NE (NE, NE)	34.4% (18.7%, 50.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.32 (0.775, 2.250)	
p-value of 2-sided stratified log-rank test	0.2915	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	36	26
0	22 (61.1%)	16 (61.5%)
1	7 (19.4%)	6 (23.1%)
2	2 (5.6%)	1 (3.8%)
3	2 (5.6%)	2 (7.7%)
>=4	3 (8.3%)	1 (3.8%)
p-value from Interaction Test[c]	0.4011	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	109 (80.7%)	116 (84.7%)
Censored	26 (19.3%)	21 (15.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.2 (0.8, 1.4)	1.4 (0.9, 2.1)
50%	3.5 (2.6, 4.6)	4.7 (3.4, 9.3)
75%	20.1 (9.9, 32.1)	14.8 (12.5, 21.2)
Survival probability (95% CI) at		
Month 6	39.3% (31.0%, 47.6%)	48.6% (39.9%, 56.7%)
Month 12	32.0% (24.1%, 40.1%)	34.0% (26.0%, 42.0%)
Month 18	29.3% (21.6%, 37.3%)	20.8% (14.4%, 28.1%)
Month 24	23.8% (16.7%, 31.7%)	15.0% (9.5%, 21.8%)
Month 30	19.3% (12.7%, 26.8%)	13.3% (8.0%, 19.8%)
Month 36	17.2% (10.9%, 24.6%)	11.1% (6.2%, 17.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.95 (0.726, 1.238)	
p-value of 2-sided stratified log-rank test	0.6817	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	109	116
0	80 (73.4%)	92 (79.3%)
1	12 (11.0%)	11 (9.5%)
2	10 (9.2%)	6 (5.2%)
3	5 (4.6%)	3 (2.6%)
>=4	2 (1.8%)	4 (3.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	48 (84.2%)	36 (76.6%)
Censored	9 (15.8%)	11 (23.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.5)	0.9 (0.7, 2.9)
50%	2.8 (1.5, 4.9)	8.7 (2.8, 17.3)
75%	17.0 (4.9, 28.0)	24.6 (16.7, NE)
Survival probability (95% CI) at		
Month 6	33.0% (20.8%, 45.6%)	53.3% (37.9%, 66.6%)
Month 12	29.1% (17.6%, 41.6%)	44.1% (29.4%, 57.9%)
Month 18	23.3% (12.9%, 35.3%)	34.8% (21.3%, 48.7%)
Month 24	17.2% (8.4%, 28.7%)	25.6% (13.8%, 39.0%)
Month 30	10.8% (4.1%, 21.2%)	23.2% (12.1%, 36.5%)
Month 36	NE (NE, NE)	17.2% (7.4%, 30.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.28 (0.819, 2.013)	
p-value of 2-sided stratified log-rank test	0.2637	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	48	36
0	34 (70.8%)	26 (72.2%)
1	7 (14.6%)	6 (16.7%)
2	2 (4.2%)	1 (2.8%)
3	2 (4.2%)	2 (5.6%)
>=4	3 (6.3%)	1 (2.8%)
p-value from Interaction Test[c]	0.1842	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	28 (20.7%)	33 (24.1%)
Censored	107 (79.3%)	104 (75.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (3.7, NE)	10.9 (1.2, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	79.7% (71.6%, 85.7%)	75.3% (66.9%, 81.8%)
Month 12	78.7% (70.4%, 84.9%)	74.1% (65.5%, 80.9%)
Month 18	78.7% (70.4%, 84.9%)	74.1% (65.5%, 80.9%)
Month 24	78.7% (70.4%, 84.9%)	74.1% (65.5%, 80.9%)
Month 30	78.7% (70.4%, 84.9%)	74.1% (65.5%, 80.9%)
Month 36	75.9% (65.7%, 83.4%)	74.1% (65.5%, 80.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.18 (0.712, 1.972)	
p-value of 2-sided stratified log-rank test	0.5199	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	28	33
0	11 (39.3%)	11 (33.3%)
1	3 (10.7%)	2 (6.1%)
2	2 (7.1%)	6 (18.2%)
3	3 (10.7%)	4 (12.1%)
>=4	9 (32.1%)	10 (30.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	19 (33.3%)	10 (21.3%)
Censored	38 (66.7%)	37 (78.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.9, 4.8)	NE (0.9, NE)
50%	NE (4.8, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	62.7% (47.8%, 74.4%)	80.0% (65.1%, 89.1%)
Month 12	62.7% (47.8%, 74.4%)	77.3% (61.9%, 87.1%)
Month 18	62.7% (47.8%, 74.4%)	77.3% (61.9%, 87.1%)
Month 24	62.7% (47.8%, 74.4%)	77.3% (61.9%, 87.1%)
Month 30	62.7% (47.8%, 74.4%)	77.3% (61.9%, 87.1%)
Month 36	62.7% (47.8%, 74.4%)	77.3% (61.9%, 87.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Nausea & Vomiting Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.61 (0.279, 1.345)	
p-value of 2-sided stratified log-rank test	0.2220	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	19	10
0	6 (31.6%)	2 (20.0%)
1	4 (21.1%)	2 (20.0%)
2	2 (10.5%)	0
3	1 (5.3%)	1 (10.0%)
>=4	6 (31.6%)	5 (50.0%)
p-value from Interaction Test[c]	0.1179	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	101 (74.8%)	93 (67.9%)
Censored	34 (25.2%)	44 (32.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.1 (0.8, 1.4)	1.2 (0.9, 2.1)
50%	4.2 (2.8, 7.4)	4.4 (3.4, 6.9)
75%	18.1 (11.7, 34.2)	18.1 (11.2, NE)
Survival probability (95% CI) at		
Month 6	42.9% (34.2%, 51.2%)	45.1% (36.2%, 53.5%)
Month 12	31.9% (23.8%, 40.3%)	30.2% (21.9%, 38.8%)
Month 18	26.8% (19.0%, 35.1%)	25.3% (17.4%, 34.0%)
Month 24	19.3% (12.2%, 27.5%)	18.7% (11.2%, 27.7%)
Month 30	19.3% (12.2%, 27.5%)	18.7% (11.2%, 27.7%)
Month 36	11.8% (5.6%, 20.4%)	18.7% (11.2%, 27.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.98 (0.735, 1.302)	
p-value of 2-sided stratified log-rank test	0.8792	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	101	93
0	57 (56.4%)	47 (50.5%)
1	9 (8.9%)	21 (22.6%)
2	14 (13.9%)	11 (11.8%)
3	5 (5.0%)	1 (1.1%)
>=4	16 (15.8%)	13 (14.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	34 (59.6%)	34 (72.3%)
Censored	23 (40.4%)	13 (27.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.1)	1.0 (0.8, 2.1)
50%	3.5 (2.1, 8.8)	3.5 (2.1, 7.1)
75%	15.3 (7.6, NE)	13.4 (6.1, NE)
Survival probability (95% CI) at		
Month 6	40.7% (26.5%, 54.5%)	39.4% (25.1%, 53.3%)
Month 12	30.2% (16.5%, 45.1%)	28.5% (15.7%, 42.7%)
Month 18	21.1% (8.6%, 37.3%)	24.9% (12.6%, 39.3%)
Month 24	21.1% (8.6%, 37.3%)	18.7% (6.8%, 35.1%)
Month 30	21.1% (8.6%, 37.3%)	18.7% (6.8%, 35.1%)
Month 36	NE (NE, NE)	0 (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.90 (0.548, 1.463)	
p-value of 2-sided stratified log-rank test	0.6672	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	34	34
0	20 (58.8%)	16 (47.1%)
1	2 (5.9%)	7 (20.6%)
2	9 (26.5%)	2 (5.9%)
3	0	2 (5.9%)
>=4	3 (8.8%)	7 (20.6%)
p-value from Interaction Test[c]	0.7592	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	116 (85.9%)	121 (88.3%)
Censored	19 (14.1%)	16 (11.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.1 (0.8, 1.4)	1.2 (0.8, 2.1)
50%	4.2 (2.8, 7.0)	4.4 (3.4, 6.9)
75%	17.4 (11.1, 20.7)	12.6 (8.8, 16.1)
Survival probability (95% CI) at		
Month 6	42.9% (34.3%, 51.2%)	43.7% (35.2%, 51.9%)
Month 12	29.7% (22.0%, 37.8%)	25.8% (18.7%, 33.6%)
Month 18	23.9% (16.9%, 31.7%)	16.2% (10.4%, 23.0%)
Month 24	14.5% (9.0%, 21.4%)	8.9% (4.7%, 14.6%)
Month 30	12.8% (7.6%, 19.4%)	8.1% (4.2%, 13.7%)
Month 36	7.2% (3.3%, 13.3%)	8.1% (4.2%, 13.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.88 (0.677, 1.136)	
p-value of 2-sided stratified log-rank test	0.3161	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	116	121
0	72 (62.1%)	75 (62.0%)
1	9 (7.8%)	21 (17.4%)
2	14 (12.1%)	11 (9.1%)
3	5 (4.3%)	1 (0.8%)
>=4	16 (13.8%)	13 (10.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	49 (86.0%)	42 (89.4%)
Censored	8 (14.0%)	5 (10.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.1)	1.0 (0.8, 2.1)
50%	3.5 (2.1, 5.5)	3.5 (2.1, 6.1)
75%	8.8 (5.5, 15.3)	13.4 (5.6, 21.7)
Survival probability (95% CI) at		
Month 6	34.6% (22.2%, 47.4%)	37.8% (23.9%, 51.6%)
Month 12	22.4% (12.2%, 34.5%)	28.9% (16.6%, 42.4%)
Month 18	10.2% (3.8%, 20.3%)	20.0% (9.9%, 32.6%)
Month 24	8.1% (2.6%, 17.8%)	13.0% (5.1%, 24.6%)
Month 30	6.1% (1.6%, 15.1%)	10.4% (3.5%, 21.6%)
Month 36	NE (NE, NE)	0 (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.06 (0.691, 1.627)	
p-value of 2-sided stratified log-rank test	0.7784	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	49	42
0	35 (71.4%)	24 (57.1%)
1	2 (4.1%)	7 (16.7%)
2	9 (18.4%)	2 (4.8%)
3	0	2 (4.8%)
>=4	3 (6.1%)	7 (16.7%)
p-value from Interaction Test[c]	0.5169	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	87 (64.4%)	78 (56.9%)
Censored	48 (35.6%)	59 (43.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 1.0)
50%	1.4 (1.4, 3.5)	2.8 (1.4, 10.2)
75%	NE (12.5, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	36.7% (28.5%, 45.0%)	43.9% (35.2%, 52.3%)
Month 12	33.7% (25.6%, 42.1%)	41.0% (32.3%, 49.4%)
Month 18	32.6% (24.4%, 41.0%)	38.5% (29.8%, 47.2%)
Month 24	31.2% (23.0%, 39.7%)	38.5% (29.8%, 47.2%)
Month 30	31.2% (23.0%, 39.7%)	38.5% (29.8%, 47.2%)
Month 36	31.2% (23.0%, 39.7%)	38.5% (29.8%, 47.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.80 (0.584, 1.087)	
p-value of 2-sided stratified log-rank test	0.1492	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	87	78
0	40 (46.0%)	31 (39.7%)
1	14 (16.1%)	17 (21.8%)
2	9 (10.3%)	7 (9.0%)
3	4 (4.6%)	4 (5.1%)
>=4	20 (23.0%)	19 (24.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	35 (61.4%)	16 (34.0%)
Censored	22 (38.6%)	31 (66.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.8, 1.4)	1.4 (0.8, NE)
50%	2.9 (1.4, 11.4)	NE (15.7, NE)
75%	NE (11.4, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	41.0% (27.2%, 54.2%)	66.6% (50.8%, 78.3%)
Month 12	36.1% (22.9%, 49.6%)	66.6% (50.8%, 78.3%)
Month 18	31.1% (18.5%, 44.7%)	63.1% (46.6%, 75.7%)
Month 24	31.1% (18.5%, 44.7%)	63.1% (46.6%, 75.7%)
Month 30	31.1% (18.5%, 44.7%)	63.1% (46.6%, 75.7%)
Month 36	NE (NE, NE)	63.1% (46.6%, 75.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Pain Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.39 (0.208, 0.718)	
p-value of 2-sided stratified log-rank test	0.0019	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	35	16
0	18 (51.4%)	3 (18.8%)
1	3 (8.6%)	1 (6.3%)
2	5 (14.3%)	3 (18.8%)
3	0	0
>=4	9 (25.7%)	9 (56.3%)
p-value from Interaction Test[c]	0.0592	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	91 (67.4%)	94 (68.6%)
Censored	44 (32.6%)	43 (31.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.2)	1.6 (1.4, 2.1)
50%	3.7 (2.9, 6.9)	3.8 (2.8, 6.7)
75%	28.5 (20.5, NE)	19.3 (10.0, NE)
Survival probability (95% CI) at		
Month 6	44.4% (35.7%, 52.8%)	42.4% (33.7%, 50.9%)
Month 12	37.8% (29.2%, 46.3%)	29.3% (21.1%, 37.9%)
Month 18	34.2% (25.7%, 42.9%)	26.8% (18.8%, 35.4%)
Month 24	31.1% (22.5%, 40.1%)	22.8% (15.1%, 31.5%)
Month 30	21.6% (13.2%, 31.5%)	18.7% (11.0%, 27.9%)
Month 36	16.2% (8.0%, 27.0%)	14.9% (7.0%, 25.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.94 (0.705, 1.267)	
p-value of 2-sided stratified log-rank test	0.6419	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	91	94
0	52 (57.1%)	44 (46.8%)
1	13 (14.3%)	22 (23.4%)
2	7 (7.7%)	5 (5.3%)
3	5 (5.5%)	11 (11.7%)
>=4	14 (15.4%)	12 (12.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	29 (50.9%)	27 (57.4%)
Censored	28 (49.1%)	20 (42.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (0.8, 2.2)	1.2 (0.8, 2.8)
50%	4.2 (2.2, NE)	6.7 (2.8, 27.9)
75%	NE (17.3, NE)	NE (24.7, NE)
Survival probability (95% CI) at		
Month 6	49.0% (34.7%, 61.8%)	50.8% (35.4%, 64.3%)
Month 12	49.0% (34.7%, 61.8%)	45.2% (30.0%, 59.3%)
Month 18	39.0% (24.3%, 53.5%)	41.7% (26.5%, 56.3%)
Month 24	39.0% (24.3%, 53.5%)	41.7% (26.5%, 56.3%)
Month 30	39.0% (24.3%, 53.5%)	29.8% (13.8%, 47.7%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.91 (0.530, 1.580)	
p-value of 2-sided stratified log-rank test	0.7548	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	29	27
0	13 (44.8%)	16 (59.3%)
1	4 (13.8%)	1 (3.7%)
2	4 (13.8%)	2 (7.4%)
3	1 (3.4%)	1 (3.7%)
>=4	7 (24.1%)	7 (25.9%)
p-value from Interaction Test[c]	0.8260	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	111 (82.2%)	117 (85.4%)
Censored	24 (17.8%)	20 (14.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.1)	1.6 (1.4, 2.1)
50%	3.6 (2.9, 6.8)	4.0 (2.9, 6.7)
75%	20.5 (12.9, 27.6)	12.6 (9.6, 22.0)
Survival probability (95% CI) at		
Month 6	43.4% (34.8%, 51.7%)	42.1% (33.6%, 50.3%)
Month 12	33.4% (25.3%, 41.6%)	26.5% (19.1%, 34.3%)
Month 18	28.0% (20.4%, 36.1%)	19.8% (13.4%, 27.2%)
Month 24	22.0% (15.0%, 30.0%)	14.5% (8.9%, 21.4%)
Month 30	14.0% (8.3%, 21.2%)	9.6% (5.1%, 15.9%)
Month 36	7.6% (3.3%, 14.4%)	8.0% (3.7%, 14.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.94 (0.723, 1.226)	
p-value of 2-sided stratified log-rank test	0.5986	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	111	117
0	72 (64.9%)	67 (57.3%)
1	13 (11.7%)	22 (18.8%)
2	7 (6.3%)	5 (4.3%)
3	5 (4.5%)	11 (9.4%)
>=4	14 (12.6%)	12 (10.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	45 (78.9%)	37 (78.7%)
Censored	12 (21.1%)	10 (21.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.2)	1.2 (0.8, 2.8)
50%	3.9 (2.2, 12.1)	6.0 (2.8, 12.5)
75%	17.3 (8.0, NE)	20.0 (10.3, NE)
Survival probability (95% CI) at		
Month 6	43.0% (29.7%, 55.6%)	51.1% (35.8%, 64.5%)
Month 12	37.4% (24.7%, 50.1%)	37.8% (23.9%, 51.6%)
Month 18	24.3% (13.9%, 36.3%)	30.8% (18.1%, 44.5%)
Month 24	22.4% (12.4%, 34.3%)	21.1% (10.4%, 34.2%)
Month 30	16.3% (7.8%, 27.5%)	15.0% (6.0%, 27.9%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.05 (0.669, 1.651)	
p-value of 2-sided stratified log-rank test	0.8257	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	45	37
0	29 (64.4%)	26 (70.3%)
1	4 (8.9%)	1 (2.7%)
2	4 (8.9%)	2 (5.4%)
3	1 (2.2%)	1 (2.7%)
>=4	7 (15.6%)	7 (18.9%)
p-value from Interaction Test[c]	0.8117	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	36 (26.7%)	25 (18.2%)
Censored	99 (73.3%)	112 (81.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	13.7 (2.2, NE)	NE (12.7, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	76.6% (68.3%, 83.1%)	85.3% (77.9%, 90.4%)
Month 12	75.7% (67.2%, 82.3%)	83.2% (75.3%, 88.8%)
Month 18	72.4% (63.4%, 79.5%)	80.8% (72.3%, 86.9%)
Month 24	69.6% (60.0%, 77.3%)	77.7% (68.2%, 84.6%)
Month 30	69.6% (60.0%, 77.3%)	77.7% (68.2%, 84.6%)
Month 36	69.6% (60.0%, 77.3%)	77.7% (68.2%, 84.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.63 (0.374, 1.056)	
p-value of 2-sided stratified log-rank test	0.0798	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	36	25
0	17 (47.2%)	9 (36.0%)
1	4 (11.1%)	7 (28.0%)
2	5 (13.9%)	1 (4.0%)
3	2 (5.6%)	3 (12.0%)
>=4	8 (22.2%)	5 (20.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	18 (31.6%)	13 (27.7%)
Censored	39 (68.4%)	34 (72.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.9 (1.4, 30.1)	5.6 (1.0, NE)
50%	NE (11.2, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	71.6% (56.6%, 82.2%)	73.0% (57.4%, 83.7%)
Month 12	62.2% (45.6%, 75.1%)	70.4% (54.5%, 81.7%)
Month 18	62.2% (45.6%, 75.1%)	70.4% (54.5%, 81.7%)
Month 24	62.2% (45.6%, 75.1%)	70.4% (54.5%, 81.7%)
Month 30	62.2% (45.6%, 75.1%)	70.4% (54.5%, 81.7%)
Month 36	57.4% (39.5%, 71.8%)	70.4% (54.5%, 81.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Dyspnea Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.81 (0.395, 1.676)	
p-value of 2-sided stratified log-rank test	0.5754	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	18	13
0	12 (66.7%)	5 (38.5%)
1	1 (5.6%)	2 (15.4%)
2	3 (16.7%)	1 (7.7%)
3	0	0
>=4	2 (11.1%)	5 (38.5%)
p-value from Interaction Test[c]	0.7005	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	72 (53.3%)	72 (52.6%)
Censored	63 (46.7%)	65 (47.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.0, 2.8)	1.7 (0.9, 2.1)
50%	11.3 (3.5, 26.9)	6.4 (3.5, 29.3)
75%	NE (41.7, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	53.9% (44.9%, 62.1%)	50.5% (41.5%, 58.8%)
Month 12	48.0% (38.8%, 56.5%)	44.1% (34.9%, 52.8%)
Month 18	45.6% (36.4%, 54.4%)	42.7% (33.5%, 51.6%)
Month 24	44.3% (34.9%, 53.2%)	41.0% (31.6%, 50.2%)
Month 30	39.6% (30.0%, 49.0%)	38.6% (28.7%, 48.4%)
Month 36	39.6% (30.0%, 49.0%)	38.6% (28.7%, 48.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.88 (0.636, 1.226)	
p-value of 2-sided stratified log-rank test	0.4764	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	72	72
0	46 (63.9%)	54 (75.0%)
1	12 (16.7%)	9 (12.5%)
2	7 (9.7%)	4 (5.6%)
3	1 (1.4%)	0
>=4	6 (8.3%)	5 (6.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	28 (49.1%)	24 (51.1%)
Censored	29 (50.9%)	23 (48.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.2 (0.8, 2.8)	1.4 (0.8, 2.8)
50%	8.6 (2.8, NE)	12.6 (2.3, NE)
75%	NE (15.2, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	53.9% (38.9%, 66.7%)	52.6% (36.9%, 66.0%)
Month 12	42.2% (27.2%, 56.5%)	52.6% (36.9%, 66.0%)
Month 18	39.0% (24.1%, 53.6%)	42.8% (27.1%, 57.7%)
Month 24	39.0% (24.1%, 53.6%)	42.8% (27.1%, 57.7%)
Month 30	39.0% (24.1%, 53.6%)	42.8% (27.1%, 57.7%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.01 (0.581, 1.767)	
p-value of 2-sided stratified log-rank test	0.9479	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	28	24
0	15 (53.6%)	7 (29.2%)
1	6 (21.4%)	7 (29.2%)
2	2 (7.1%)	3 (12.5%)
3	2 (7.1%)	2 (8.3%)
>=4	3 (10.7%)	5 (20.8%)
p-value from Interaction Test[c]	0.6947	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	99 (73.3%)	113 (82.5%)
Censored	36 (26.7%)	24 (17.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.9 (1.0, 2.8)	1.7 (0.9, 2.1)
50%	8.4 (3.5, 13.2)	4.8 (3.5, 9.7)
75%	29.8 (20.1, NE)	19.9 (13.2, 27.0)
Survival probability (95% CI) at		
Month 6	53.4% (44.4%, 61.5%)	47.8% (39.1%, 56.0%)
Month 12	43.2% (34.5%, 51.7%)	35.7% (27.5%, 43.9%)
Month 18	38.8% (30.2%, 47.3%)	25.7% (18.5%, 33.6%)
Month 24	32.2% (24.0%, 40.7%)	20.7% (14.0%, 28.2%)
Month 30	24.6% (17.2%, 32.8%)	15.3% (9.5%, 22.3%)
Month 36	20.5% (13.5%, 28.5%)	13.1% (7.7%, 19.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.75 (0.571, 0.987)	
p-value of 2-sided stratified log-rank test	0.0404	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	99	113
0	73 (73.7%)	95 (84.1%)
1	12 (12.1%)	9 (8.0%)
2	7 (7.1%)	4 (3.5%)
3	1 (1.0%)	0
>=4	6 (6.1%)	5 (4.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	43 (75.4%)	36 (76.6%)
Censored	14 (24.6%)	11 (23.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.0 (0.9, 2.8)	1.4 (0.8, 2.8)
50%	5.7 (2.8, 10.1)	6.0 (2.3, 16.7)
75%	15.3 (10.1, NE)	24.6 (16.2, NE)
Survival probability (95% CI) at		
Month 6	46.5% (32.8%, 59.1%)	51.1% (35.8%, 64.5%)
Month 12	34.4% (21.9%, 47.2%)	44.4% (29.7%, 58.2%)
Month 18	24.2% (13.6%, 36.6%)	32.9% (19.8%, 46.7%)
Month 24	22.2% (12.0%, 34.4%)	25.5% (13.7%, 39.1%)
Month 30	17.8% (8.7%, 29.5%)	22.9% (11.7%, 36.3%)
Month 36	NE (NE, NE)	22.9% (11.7%, 36.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.13 (0.717, 1.797)	
p-value of 2-sided stratified log-rank test	0.5765	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	43	36
0	30 (69.8%)	19 (52.8%)
1	6 (14.0%)	7 (19.4%)
2	2 (4.7%)	3 (8.3%)
3	2 (4.7%)	2 (5.6%)
>=4	3 (7.0%)	5 (13.9%)
p-value from Interaction Test[c]	0.1822	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	78 (57.8%)	77 (56.2%)
Censored	57 (42.2%)	60 (43.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 1.6)	0.9 (0.8, 1.4)
50%	4.2 (2.3, 9.7)	6.0 (2.1, 11.1)
75%	NE (NE, NE)	NE (31.8, NE)
Survival probability (95% CI) at		
Month 6	46.4% (37.6%, 54.8%)	50.0% (41.0%, 58.4%)
Month 12	39.8% (31.1%, 48.4%)	39.5% (30.4%, 48.4%)
Month 18	39.8% (31.1%, 48.4%)	38.1% (29.0%, 47.1%)
Month 24	39.8% (31.1%, 48.4%)	38.1% (29.0%, 47.1%)
Month 30	37.8% (28.7%, 46.8%)	36.3% (27.0%, 45.6%)
Month 36	35.4% (26.0%, 45.0%)	33.3% (23.3%, 43.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.01 (0.734, 1.391)	
p-value of 2-sided stratified log-rank test	0.9914	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	78	77
0	30 (38.5%)	34 (44.2%)
1	15 (19.2%)	10 (13.0%)
2	7 (9.0%)	8 (10.4%)
3	5 (6.4%)	7 (9.1%)
>=4	21 (26.9%)	18 (23.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	26 (45.6%)	22 (46.8%)
Censored	31 (54.4%)	25 (53.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.8, 1.7)	1.6 (0.8, 4.2)
50%	3.0 (1.6, NE)	7.0 (3.5, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	49.8% (35.5%, 62.5%)	54.7% (38.9%, 68.0%)
Month 12	49.8% (35.5%, 62.5%)	49.7% (34.1%, 63.5%)
Month 18	49.8% (35.5%, 62.5%)	49.7% (34.1%, 63.5%)
Month 24	49.8% (35.5%, 62.5%)	49.7% (34.1%, 63.5%)
Month 30	49.8% (35.5%, 62.5%)	49.7% (34.1%, 63.5%)
Month 36	49.8% (35.5%, 62.5%)	49.7% (34.1%, 63.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Insomnia Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.95 (0.535, 1.697)	
p-value of 2-sided stratified log-rank test	0.8623	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	26	22
0	8 (30.8%)	7 (31.8%)
1	5 (19.2%)	4 (18.2%)
2	2 (7.7%)	5 (22.7%)
3	1 (3.8%)	0
>=4	10 (38.5%)	6 (27.3%)
p-value from Interaction Test[c]	0.8130	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	84 (62.2%)	86 (62.8%)
Censored	51 (37.8%)	51 (37.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.9, 3.4)	1.4 (1.2, 2.2)
50%	7.1 (4.4, 12.5)	8.3 (3.3, 11.6)
75%	NE (21.3, NE)	32.2 (22.7, NE)
Survival probability (95% CI) at		
Month 6	53.4% (44.4%, 61.6%)	52.1% (43.0%, 60.4%)
Month 12	42.2% (33.2%, 50.8%)	40.0% (31.0%, 48.8%)
Month 18	39.0% (30.1%, 47.8%)	34.1% (25.2%, 43.1%)
Month 24	30.5% (21.9%, 39.5%)	32.7% (23.9%, 41.8%)
Month 30	29.2% (20.7%, 38.3%)	27.1% (18.5%, 36.3%)
Month 36	29.2% (20.7%, 38.3%)	23.6% (15.1%, 33.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.88 (0.651, 1.194)	
p-value of 2-sided stratified log-rank test	0.4122	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	84	86
0	51 (60.7%)	50 (58.1%)
1	12 (14.3%)	15 (17.4%)
2	9 (10.7%)	5 (5.8%)
3	7 (8.3%)	6 (7.0%)
>=4	5 (6.0%)	10 (11.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	30 (52.6%)	29 (61.7%)
Censored	27 (47.4%)	18 (38.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 1.6)	2.1 (0.9, 2.8)
50%	8.6 (1.5, 23.8)	8.7 (2.8, 28.4)
75%	NE (19.4, NE)	33.9 (16.2, NE)
Survival probability (95% CI) at		
Month 6	51.6% (37.2%, 64.2%)	55.3% (39.7%, 68.4%)
Month 12	45.7% (31.0%, 59.2%)	45.3% (30.1%, 59.3%)
Month 18	42.1% (27.3%, 56.3%)	37.1% (22.7%, 51.6%)
Month 24	34.1% (19.2%, 49.6%)	37.1% (22.7%, 51.6%)
Month 30	34.1% (19.2%, 49.6%)	32.5% (17.9%, 47.9%)
Month 36	NE (NE, NE)	24.4% (9.2%, 43.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.10 (0.652, 1.842)	
p-value of 2-sided stratified log-rank test	0.7401	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	30	29
0	16 (53.3%)	17 (58.6%)
1	9 (30.0%)	4 (13.8%)
2	1 (3.3%)	5 (17.2%)
3	1 (3.3%)	1 (3.4%)
>=4	3 (10.0%)	2 (6.9%)
p-value from Interaction Test[c]	0.4520	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	99 (73.3%)	118 (86.1%)
Censored	36 (26.7%)	19 (13.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.0 (0.9, 2.8)	1.4 (1.2, 2.2)
50%	7.1 (4.4, 10.5)	5.5 (3.4, 9.7)
75%	26.3 (19.2, NE)	17.7 (12.2, 27.2)
Survival probability (95% CI) at		
Month 6	53.4% (44.5%, 61.6%)	48.5% (39.9%, 56.7%)
Month 12	38.3% (29.8%, 46.8%)	33.4% (25.5%, 41.4%)
Month 18	34.8% (26.5%, 43.2%)	24.3% (17.4%, 31.8%)
Month 24	26.3% (18.7%, 34.5%)	20.4% (14.0%, 27.6%)
Month 30	23.5% (16.2%, 31.5%)	14.9% (9.4%, 21.5%)
Month 36	19.9% (13.0%, 27.9%)	12.1% (7.1%, 18.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.80 (0.608, 1.043)	
p-value of 2-sided stratified log-rank test	0.0954	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	99	118
0	66 (66.7%)	82 (69.5%)
1	12 (12.1%)	15 (12.7%)
2	9 (9.1%)	5 (4.2%)
3	7 (7.1%)	6 (5.1%)
>=4	5 (5.1%)	10 (8.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	48 (84.2%)	34 (72.3%)
Censored	9 (15.8%)	13 (27.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 1.6)	2.1 (0.9, 2.8)
50%	2.9 (1.5, 7.0)	8.7 (2.8, 16.7)
75%	18.7 (6.8, 29.0)	31.7 (16.2, NE)
Survival probability (95% CI) at		
Month 6	43.3% (30.0%, 55.9%)	55.6% (40.0%, 68.6%)
Month 12	30.1% (18.5%, 42.6%)	44.1% (29.3%, 57.9%)
Month 18	26.4% (15.5%, 38.5%)	34.8% (21.2%, 48.7%)
Month 24	18.8% (9.7%, 30.2%)	30.0% (17.2%, 43.8%)
Month 30	13.2% (5.8%, 23.6%)	26.6% (14.3%, 40.7%)
Month 36	NE (NE, NE)	17.1% (6.0%, 33.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.39 (0.887, 2.164)	
p-value of 2-sided stratified log-rank test	0.1525	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	48	34
0	34 (70.8%)	22 (64.7%)
1	9 (18.8%)	4 (11.8%)
2	1 (2.1%)	5 (14.7%)
3	1 (2.1%)	1 (2.9%)
>=4	3 (6.3%)	2 (5.9%)
p-value from Interaction Test[c]	0.0249	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	53 (39.3%)	45 (32.8%)
Censored	82 (60.7%)	92 (67.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.9, 2.9)	2.1 (1.4, 13.0)
50%	NE (19.9, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	64.4% (55.5%, 72.0%)	69.8% (61.0%, 76.9%)
Month 12	59.8% (50.7%, 67.8%)	67.9% (59.0%, 75.3%)
Month 18	59.8% (50.7%, 67.8%)	64.3% (54.9%, 72.2%)
Month 24	56.8% (47.2%, 65.4%)	64.3% (54.9%, 72.2%)
Month 30	56.8% (47.2%, 65.4%)	62.5% (52.7%, 70.9%)
Month 36	56.8% (47.2%, 65.4%)	62.5% (52.7%, 70.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.79 (0.525, 1.176)	
p-value of 2-sided stratified log-rank test	0.2410	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	53	45
0	16 (30.2%)	21 (46.7%)
1	6 (11.3%)	4 (8.9%)
2	6 (11.3%)	5 (11.1%)
3	6 (11.3%)	3 (6.7%)
>=4	19 (35.8%)	12 (26.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	17 (29.8%)	16 (34.0%)
Censored	40 (70.2%)	31 (66.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.9, NE)	0.9 (0.7, NE)
50%	NE (NE, NE)	NE (13.7, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	66.3% (51.5%, 77.6%)	66.4% (50.6%, 78.2%)
Month 12	66.3% (51.5%, 77.6%)	66.4% (50.6%, 78.2%)
Month 18	66.3% (51.5%, 77.6%)	62.9% (46.4%, 75.6%)
Month 24	66.3% (51.5%, 77.6%)	62.9% (46.4%, 75.6%)
Month 30	66.3% (51.5%, 77.6%)	62.9% (46.4%, 75.6%)
Month 36	66.3% (51.5%, 77.6%)	62.9% (46.4%, 75.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Appetite Loss Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.21 (0.604, 2.437)	
p-value of 2-sided stratified log-rank test	0.6035	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	17	16
0	7 (41.2%)	7 (43.8%)
1	2 (11.8%)	0
2	2 (11.8%)	1 (6.3%)
3	1 (5.9%)	0
>=4	5 (29.4%)	8 (50.0%)
p-value from Interaction Test[c]	0.3962	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	98 (72.6%)	86 (62.8%)
Censored	37 (27.4%)	51 (37.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.0 (0.8, 1.4)
50%	2.6 (1.5, 4.0)	3.7 (2.1, 8.7)
75%	22.4 (8.2, NE)	42.0 (17.5, NE)
Survival probability (95% CI) at		
Month 6	37.0% (28.7%, 45.3%)	46.1% (37.4%, 54.5%)
Month 12	32.5% (24.4%, 40.7%)	39.7% (31.0%, 48.2%)
Month 18	29.4% (21.5%, 37.6%)	33.3% (24.6%, 42.2%)
Month 24	23.7% (16.2%, 31.9%)	31.7% (23.0%, 40.8%)
Month 30	23.7% (16.2%, 31.9%)	31.7% (23.0%, 40.8%)
Month 36	19.3% (11.6%, 28.6%)	26.8% (17.5%, 36.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.18 (0.876, 1.582)	
p-value of 2-sided stratified log-rank test	0.2700	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	98	86
0	57 (58.2%)	43 (50.0%)
1	18 (18.4%)	14 (16.3%)
2	10 (10.2%)	11 (12.8%)
3	5 (5.1%)	7 (8.1%)
>=4	8 (8.2%)	11 (12.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	33 (57.9%)	25 (53.2%)
Censored	24 (42.1%)	22 (46.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.4 (0.7, 2.0)
50%	2.9 (1.4, 14.3)	10.0 (1.9, NE)
75%	NE (11.0, NE)	NE (12.6, NE)
Survival probability (95% CI) at		
Month 6	45.1% (31.0%, 58.3%)	53.0% (37.4%, 66.3%)
Month 12	37.2% (23.4%, 50.9%)	45.4% (29.2%, 60.2%)
Month 18	34.3% (20.8%, 48.2%)	37.8% (22.0%, 53.6%)
Month 24	30.0% (16.5%, 44.8%)	37.8% (22.0%, 53.6%)
Month 30	30.0% (16.5%, 44.8%)	37.8% (22.0%, 53.6%)
Month 36	NE (NE, NE)	37.8% (22.0%, 53.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.14 (0.666, 1.960)	
p-value of 2-sided stratified log-rank test	0.6092	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	33	25
0	19 (57.6%)	16 (64.0%)
1	2 (6.1%)	3 (12.0%)
2	6 (18.2%)	3 (12.0%)
3	3 (9.1%)	1 (4.0%)
>=4	3 (9.1%)	2 (8.0%)
p-value from Interaction Test[c]	0.9629	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	109 (80.7%)	122 (89.1%)
Censored	26 (19.3%)	15 (10.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	0.9 (0.8, 1.4)
50%	2.5 (1.5, 3.7)	3.7 (2.1, 8.3)
75%	18.7 (7.5, 31.9)	16.3 (12.6, 21.5)
Survival probability (95% CI) at		
Month 6	36.0% (27.8%, 44.2%)	45.9% (37.3%, 54.0%)
Month 12	29.3% (21.6%, 37.3%)	35.2% (27.2%, 43.3%)
Month 18	25.7% (18.3%, 33.6%)	22.2% (15.5%, 29.6%)
Month 24	20.0% (13.4%, 27.6%)	15.3% (9.8%, 22.0%)
Month 30	19.1% (12.6%, 26.6%)	13.8% (8.5%, 20.2%)
Month 36	13.6% (7.6%, 21.4%)	9.6% (5.1%, 15.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.99 (0.762, 1.290)	
p-value of 2-sided stratified log-rank test	0.9483	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	109	122
0	68 (62.4%)	79 (64.8%)
1	18 (16.5%)	14 (11.5%)
2	10 (9.2%)	11 (9.0%)
3	5 (4.6%)	7 (5.7%)
>=4	8 (7.3%)	11 (9.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	49 (86.0%)	38 (80.9%)
Censored	8 (14.0%)	9 (19.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.4 (0.7, 2.0)
50%	2.8 (1.4, 6.1)	6.0 (1.9, 12.5)
75%	14.3 (6.1, 26.5)	18.2 (11.1, 32.9)
Survival probability (95% CI) at		
Month 6	37.7% (25.0%, 50.4%)	51.1% (35.8%, 64.5%)
Month 12	30.2% (18.6%, 42.6%)	37.8% (23.9%, 51.6%)
Month 18	22.6% (12.6%, 34.5%)	26.7% (14.9%, 40.0%)
Month 24	18.9% (9.7%, 30.3%)	24.4% (13.2%, 37.6%)
Month 30	9.4% (3.5%, 19.0%)	22.2% (11.5%, 35.1%)
Month 36	NE (NE, NE)	11.4% (3.5%, 24.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.27 (0.813, 1.980)	
p-value of 2-sided stratified log-rank test	0.2799	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	49	38
0	35 (71.4%)	29 (76.3%)
1	2 (4.1%)	3 (7.9%)
2	6 (12.2%)	3 (7.9%)
3	3 (6.1%)	1 (2.6%)
>=4	3 (6.1%)	2 (5.3%)
p-value from Interaction Test[c]	0.4728	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	33 (24.4%)	39 (28.5%)
Censored	102 (75.6%)	98 (71.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	9.8 (2.6, NE)	3.9 (2.1, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	75.9% (67.5%, 82.4%)	73.3% (64.7%, 80.2%)
Month 12	74.9% (66.3%, 81.5%)	70.2% (61.1%, 77.5%)
Month 18	73.6% (64.8%, 80.5%)	67.6% (58.1%, 75.4%)
Month 24	73.6% (64.8%, 80.5%)	67.6% (58.1%, 75.4%)
Month 30	73.6% (64.8%, 80.5%)	67.6% (58.1%, 75.4%)
Month 36	73.6% (64.8%, 80.5%)	67.6% (58.1%, 75.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.21 (0.758, 1.934)	
p-value of 2-sided stratified log-rank test	0.4247	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	33	39
0	14 (42.4%)	18 (46.2%)
1	4 (12.1%)	2 (5.1%)
2	3 (9.1%)	8 (20.5%)
3	3 (9.1%)	2 (5.1%)
>=4	9 (27.3%)	9 (23.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	16 (28.1%)	9 (19.1%)
Censored	41 (71.9%)	38 (80.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.3 (0.9, NE)	NE (1.6, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	70.9% (56.3%, 81.3%)	82.0% (67.2%, 90.6%)
Month 12	68.1% (53.1%, 79.2%)	79.4% (64.0%, 88.7%)
Month 18	68.1% (53.1%, 79.2%)	79.4% (64.0%, 88.7%)
Month 24	68.1% (53.1%, 79.2%)	79.4% (64.0%, 88.7%)
Month 30	68.1% (53.1%, 79.2%)	79.4% (64.0%, 88.7%)
Month 36	68.1% (53.1%, 79.2%)	79.4% (64.0%, 88.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Constipation Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.70 (0.302, 1.626)	
p-value of 2-sided stratified log-rank test	0.4014	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	16	9
0	8 (50.0%)	4 (44.4%)
1	2 (12.5%)	0
2	1 (6.3%)	1 (11.1%)
3	1 (6.3%)	0
>=4	4 (25.0%)	4 (44.4%)
p-value from Interaction Test[c]	0.1326	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	82 (60.7%)	83 (60.6%)
Censored	53 (39.3%)	54 (39.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.7 (1.4, 2.8)	2.3 (1.4, 3.5)
50%	5.6 (3.6, 15.9)	8.8 (5.6, 11.8)
75%	NE (25.3, NE)	30.2 (21.1, NE)
Survival probability (95% CI) at		
Month 6	48.3% (39.4%, 56.7%)	57.4% (48.1%, 65.6%)
Month 12	41.9% (33.0%, 50.4%)	39.4% (30.0%, 48.6%)
Month 18	39.5% (30.6%, 48.2%)	36.8% (27.5%, 46.1%)
Month 24	35.3% (26.4%, 44.4%)	31.4% (22.3%, 40.9%)
Month 30	31.9% (22.9%, 41.4%)	25.8% (17.2%, 35.3%)
Month 36	27.7% (18.4%, 37.7%)	21.0% (12.8%, 30.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.01 (0.745, 1.383)	
p-value of 2-sided stratified log-rank test	0.9416	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	82	83
0	63 (76.8%)	55 (66.3%)
1	10 (12.2%)	14 (16.9%)
2	5 (6.1%)	6 (7.2%)
3	0	3 (3.6%)
>=4	4 (4.9%)	5 (6.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	32 (56.1%)	17 (36.2%)
Censored	25 (43.9%)	30 (63.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 2.2)	4.3 (2.1, 11.9)
50%	6.5 (2.2, 21.9)	NE (9.7, NE)
75%	29.9 (12.7, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	55.2% (40.6%, 67.7%)	72.9% (57.2%, 83.6%)
Month 12	43.6% (28.6%, 57.7%)	60.9% (43.8%, 74.2%)
Month 18	36.0% (21.0%, 51.2%)	60.9% (43.8%, 74.2%)
Month 24	26.2% (11.9%, 43.1%)	55.8% (37.4%, 70.8%)
Month 30	21.0% (7.9%, 38.3%)	55.8% (37.4%, 70.8%)
Month 36	NE (NE, NE)	55.8% (37.4%, 70.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	2.36 (1.279, 4.365)	
p-value of 2-sided stratified log-rank test	0.0048	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	32	17
0	22 (68.8%)	11 (64.7%)
1	5 (15.6%)	2 (11.8%)
2	3 (9.4%)	3 (17.6%)
3	1 (3.1%)	1 (5.9%)
>=4	1 (3.1%)	0
p-value from Interaction Test[c]	0.0074	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	104 (77.0%)	117 (85.4%)
Censored	31 (23.0%)	20 (14.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (1.1, 2.8)	2.3 (1.4, 3.4)
50%	5.2 (3.6, 9.3)	8.1 (5.4, 10.0)
75%	25.3 (18.2, 32.1)	18.1 (12.6, 25.1)
Survival probability (95% CI) at		
Month 6	48.0% (39.2%, 56.3%)	54.9% (46.0%, 62.9%)
Month 12	37.3% (29.0%, 45.7%)	33.7% (25.8%, 41.9%)
Month 18	33.7% (25.5%, 42.0%)	25.1% (18.0%, 32.8%)
Month 24	26.8% (19.2%, 35.1%)	19.4% (13.1%, 26.7%)
Month 30	19.9% (13.1%, 27.7%)	14.6% (9.1%, 21.3%)
Month 36	14.4% (8.5%, 21.8%)	10.1% (5.5%, 16.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.93 (0.713, 1.219)	
p-value of 2-sided stratified log-rank test	0.5924	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	104	117
0	85 (81.7%)	89 (76.1%)
1	10 (9.6%)	14 (12.0%)
2	5 (4.8%)	6 (5.1%)
3	0	3 (2.6%)
>=4	4 (3.8%)	5 (4.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	50 (87.7%)	32 (68.1%)
Censored	7 (12.3%)	15 (31.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 2.2)	3.8 (2.1, 8.3)
50%	5.3 (2.2, 7.0)	13.4 (7.6, 22.3)
75%	13.0 (6.8, 23.1)	36.5 (22.1, NE)
Survival probability (95% CI) at		
Month 6	46.9% (33.3%, 59.4%)	68.9% (53.2%, 80.2%)
Month 12	28.2% (16.9%, 40.5%)	50.6% (35.2%, 64.2%)
Month 18	16.9% (8.3%, 28.0%)	43.5% (28.7%, 57.4%)
Month 24	13.1% (5.8%, 23.6%)	32.9% (19.3%, 47.2%)
Month 30	7.5% (2.4%, 16.5%)	32.9% (19.3%, 47.2%)
Month 36	NE (NE, NE)	28.2% (14.6%, 43.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	2.23 (1.398, 3.569)	
p-value of 2-sided stratified log-rank test	0.0006	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	50	32
0	40 (80.0%)	26 (81.3%)
1	5 (10.0%)	2 (6.3%)
2	3 (6.0%)	3 (9.4%)
3	1 (2.0%)	1 (3.1%)
>=4	1 (2.0%)	0
p-value from Interaction Test[c]	0.0016	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	26 (19.3%)	24 (17.5%)
Censored	109 (80.7%)	113 (82.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (2.2, NE)	NE (8.3, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	80.8% (72.9%, 86.6%)	83.2% (75.6%, 88.6%)
Month 12	79.8% (71.7%, 85.8%)	81.2% (73.1%, 87.0%)
Month 18	79.8% (71.7%, 85.8%)	81.2% (73.1%, 87.0%)
Month 24	79.8% (71.7%, 85.8%)	81.2% (73.1%, 87.0%)
Month 30	79.8% (71.7%, 85.8%)	81.2% (73.1%, 87.0%)
Month 36	79.8% (71.7%, 85.8%)	81.2% (73.1%, 87.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.89 (0.509, 1.570)	
p-value of 2-sided stratified log-rank test	0.6857	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	26	24
0	8 (30.8%)	11 (45.8%)
1	6 (23.1%)	3 (12.5%)
2	3 (11.5%)	0
3	4 (15.4%)	3 (12.5%)
>=4	5 (19.2%)	7 (29.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	8 (14.0%)	6 (12.8%)
Censored	49 (86.0%)	41 (87.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (6.0, NE)	NE (2.1, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	85.7% (72.1%, 93.0%)	86.7% (72.7%, 93.8%)
Month 12	82.8% (68.0%, 91.1%)	86.7% (72.7%, 93.8%)
Month 18	82.8% (68.0%, 91.1%)	86.7% (72.7%, 93.8%)
Month 24	82.8% (68.0%, 91.1%)	86.7% (72.7%, 93.8%)
Month 30	82.8% (68.0%, 91.1%)	86.7% (72.7%, 93.8%)
Month 36	82.8% (68.0%, 91.1%)	86.7% (72.7%, 93.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Diarrhea Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.98 (0.332, 2.867)	
p-value of 2-sided stratified log-rank test	0.9636	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	8	6
0	0	2 (33.3%)
1	2 (25.0%)	0
2	0	1 (16.7%)
3	2 (25.0%)	1 (16.7%)
>=4	4 (50.0%)	2 (33.3%)
p-value from Interaction Test[c]	0.9397	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	60 (44.4%)	52 (38.0%)
Censored	75 (55.6%)	85 (62.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.4, 4.4)	4.4 (2.0, 8.5)
50%	27.9 (16.1, NE)	NE (19.0, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	65.4% (56.5%, 72.9%)	70.2% (61.3%, 77.5%)
Month 12	59.4% (50.3%, 67.4%)	62.9% (53.3%, 71.1%)
Month 18	57.2% (48.0%, 65.4%)	60.4% (50.5%, 68.9%)
Month 24	50.9% (41.1%, 59.8%)	55.9% (45.6%, 65.1%)
Month 30	49.4% (39.6%, 58.5%)	50.3% (39.2%, 60.4%)
Month 36	49.4% (39.6%, 58.5%)	50.3% (39.2%, 60.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.08 (0.741, 1.571)	
p-value of 2-sided stratified log-rank test	0.6934	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	60	52
0	36 (60.0%)	32 (61.5%)
1	11 (18.3%)	6 (11.5%)
2	6 (10.0%)	10 (19.2%)
3	2 (3.3%)	0
>=4	5 (8.3%)	4 (7.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	20 (35.1%)	18 (38.3%)
Censored	37 (64.9%)	29 (61.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.4 (1.4, 18.9)	11.2 (2.3, 18.1)
50%	33.4 (18.0, NE)	22.1 (16.4, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	70.3% (55.5%, 81.0%)	82.0% (67.1%, 90.6%)
Month 12	70.3% (55.5%, 81.0%)	73.9% (57.6%, 84.7%)
Month 18	67.4% (52.0%, 78.8%)	63.1% (44.9%, 76.8%)
Month 24	56.7% (39.5%, 70.7%)	48.0% (29.6%, 64.2%)
Month 30	56.7% (39.5%, 70.7%)	48.0% (29.6%, 64.2%)
Month 36	48.6% (27.9%, 66.5%)	48.0% (29.6%, 64.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.10 (0.565, 2.128)	
p-value of 2-sided stratified log-rank test	0.7927	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	20	18
0	14 (70.0%)	13 (72.2%)
1	3 (15.0%)	1 (5.6%)
2	1 (5.0%)	1 (5.6%)
3	0	0
>=4	2 (10.0%)	3 (16.7%)
p-value from Interaction Test[c]	0.9671	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	82 (60.7%)	103 (75.2%)
Censored	53 (39.3%)	34 (24.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.4, 4.2)	3.6 (2.0, 5.7)
50%	18.9 (9.8, 24.0)	13.2 (9.9, 17.7)
75%	NE (32.6, NE)	28.2 (21.9, NE)
Survival probability (95% CI) at		
Month 6	65.0% (56.2%, 72.5%)	66.3% (57.6%, 73.6%)
Month 12	57.0% (48.0%, 65.0%)	53.8% (44.9%, 61.9%)
Month 18	52.6% (43.6%, 60.9%)	40.4% (31.9%, 48.7%)
Month 24	40.5% (31.6%, 49.1%)	31.4% (23.5%, 39.5%)
Month 30	36.7% (28.0%, 45.4%)	22.9% (16.0%, 30.6%)
Month 36	33.3% (24.7%, 42.1%)	21.6% (14.8%, 29.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.76 (0.565, 1.017)	
p-value of 2-sided stratified log-rank test	0.0628	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	82	103
0	58 (70.7%)	83 (80.6%)
1	11 (13.4%)	6 (5.8%)
2	6 (7.3%)	10 (9.7%)
3	2 (2.4%)	0
>=4	5 (6.1%)	4 (3.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	43 (75.4%)	36 (76.6%)
Censored	14 (24.6%)	11 (23.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.4, 4.9)	9.4 (2.3, 13.4)
50%	12.5 (4.9, 18.7)	17.3 (12.9, 19.8)
75%	28.6 (18.7, NE)	32.4 (19.0, 36.5)
Survival probability (95% CI) at		
Month 6	61.5% (47.3%, 73.0%)	80.0% (65.1%, 89.1%)
Month 12	52.2% (38.2%, 64.4%)	66.7% (50.9%, 78.4%)
Month 18	41.0% (27.9%, 53.7%)	48.4% (33.2%, 62.0%)
Month 24	31.7% (19.9%, 44.2%)	29.6% (16.9%, 43.5%)
Month 30	21.5% (11.5%, 33.4%)	29.6% (16.9%, 43.5%)
Month 36	18.4% (8.9%, 30.6%)	21.0% (10.0%, 34.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.24 (0.787, 1.969)	
p-value of 2-sided stratified log-rank test	0.3277	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	43	36
0	37 (86.0%)	31 (86.1%)
1	3 (7.0%)	1 (2.8%)
2	1 (2.3%)	1 (2.8%)
3	0	0
>=4	2 (4.7%)	3 (8.3%)
p-value from Interaction Test[c]	0.1009	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	41 (30.4%)	33 (24.1%)
Censored	94 (69.6%)	104 (75.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.7 (2.0, 20.6)	21.1 (1.4, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	72.0% (63.3%, 78.9%)	77.8% (69.6%, 84.0%)
Month 12	69.9% (61.0%, 77.1%)	77.8% (69.6%, 84.0%)
Month 18	67.4% (58.1%, 75.1%)	75.4% (66.8%, 82.1%)
Month 24	65.9% (56.3%, 73.9%)	72.6% (63.2%, 79.9%)
Month 30	65.9% (56.3%, 73.9%)	72.6% (63.2%, 79.9%)
Month 36	65.9% (56.3%, 73.9%)	72.6% (63.2%, 79.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.81 (0.510, 1.281)	
p-value of 2-sided stratified log-rank test	0.3368	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	41	33
0	16 (39.0%)	11 (33.3%)
1	5 (12.2%)	5 (15.2%)
2	6 (14.6%)	3 (9.1%)
3	2 (4.9%)	3 (9.1%)
>=4	12 (29.3%)	11 (33.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	7 (12.3%)	8 (17.0%)
Censored	50 (87.7%)	39 (83.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (12.5, NE)	NE (3.5, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	88.5% (76.1%, 94.7%)	84.3% (69.9%, 92.2%)
Month 12	88.5% (76.1%, 94.7%)	84.3% (69.9%, 92.2%)
Month 18	85.2% (70.8%, 92.8%)	84.3% (69.9%, 92.2%)
Month 24	85.2% (70.8%, 92.8%)	79.6% (62.0%, 89.7%)
Month 30	85.2% (70.8%, 92.8%)	79.6% (62.0%, 89.7%)
Month 36	85.2% (70.8%, 92.8%)	79.6% (62.0%, 89.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Financial Difficulties Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.23 (0.439, 3.420)	
p-value of 2-sided stratified log-rank test	0.6969	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	7	8
0	1 (14.3%)	4 (50.0%)
1	1 (14.3%)	0
2	2 (28.6%)	1 (12.5%)
3	0	1 (12.5%)
>=4	3 (42.9%)	2 (25.0%)
p-value from Interaction Test[c]	0.3877	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	68 (70.1%)	58 (69.0%)
Censored	29 (29.9%)	26 (31.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 1.5)	1.4 (0.8, 2.1)
50%	2.9 (2.1, 4.1)	4.1 (2.8, 6.9)
75%	27.9 (5.7, NE)	15.5 (8.3, NE)
Survival probability (95% CI) at		
Month 6	33.9% (24.4%, 43.7%)	40.6% (29.3%, 51.5%)
Month 12	27.3% (18.0%, 37.4%)	32.9% (22.3%, 43.9%)
Month 18	25.2% (16.0%, 35.4%)	24.1% (14.6%, 35.0%)
Month 24	25.2% (16.0%, 35.4%)	17.1% (8.5%, 28.1%)
Month 30	22.7% (13.5%, 33.3%)	17.1% (8.5%, 28.1%)
Month 36	22.7% (13.5%, 33.3%)	17.1% (8.5%, 28.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.10 (0.764, 1.586)	
p-value of 2-sided stratified log-rank test	0.5923	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	68	58
0	36 (52.9%)	34 (58.6%)
1	7 (10.3%)	7 (12.1%)
2	6 (8.8%)	4 (6.9%)
3	4 (5.9%)	3 (5.2%)
>=4	15 (22.1%)	10 (17.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	67 (70.5%)	72 (72.0%)
Censored	28 (29.5%)	28 (28.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (1.4, 2.0)	1.4 (0.8, 2.1)
50%	2.9 (2.1, 4.1)	3.5 (2.3, 5.8)
75%	8.7 (4.8, NE)	20.8 (10.9, NE)
Survival probability (95% CI) at		
Month 6	32.1% (22.4%, 42.2%)	39.6% (29.7%, 49.2%)
Month 12	22.3% (13.6%, 32.5%)	33.2% (23.7%, 42.9%)
Month 18	20.1% (11.5%, 30.4%)	29.9% (20.6%, 39.8%)
Month 24	17.2% (8.9%, 27.9%)	24.3% (15.3%, 34.5%)
Month 30	13.8% (5.8%, 25.1%)	22.3% (13.4%, 32.6%)
Month 36	13.8% (5.8%, 25.1%)	14.3% (6.4%, 25.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.17 (0.831, 1.645)	
p-value of 2-sided stratified log-rank test	0.3666	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	67	72
0	33 (49.3%)	39 (54.2%)
1	13 (19.4%)	10 (13.9%)
2	6 (9.0%)	5 (6.9%)
3	4 (6.0%)	4 (5.6%)
>=4	11 (16.4%)	14 (19.4%)
p-value from Interaction Test[c]	0.8095	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	79 (81.4%)	72 (85.7%)
Censored	18 (18.6%)	12 (14.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 1.6)	1.4 (0.8, 2.1)
50%	2.9 (2.1, 4.1)	3.8 (2.8, 5.1)
75%	9.1 (5.7, 27.9)	13.8 (6.5, 19.8)
Survival probability (95% CI) at		
Month 6	33.7% (24.4%, 43.2%)	36.5% (26.1%, 46.9%)
Month 12	21.7% (13.8%, 30.8%)	28.9% (19.4%, 39.0%)
Month 18	18.9% (11.4%, 27.8%)	18.9% (11.2%, 28.1%)
Month 24	18.9% (11.4%, 27.8%)	11.7% (5.7%, 20.1%)
Month 30	14.2% (7.5%, 22.9%)	8.5% (3.5%, 16.4%)
Month 36	14.2% (7.5%, 22.9%)	8.5% (3.5%, 16.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.04 (0.745, 1.449)	
p-value of 2-sided stratified log-rank test	0.8110	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	79	72
0	47 (59.5%)	48 (66.7%)
1	7 (8.9%)	7 (9.7%)
2	6 (7.6%)	4 (5.6%)
3	4 (5.1%)	3 (4.2%)
>=4	15 (19.0%)	10 (13.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	81 (85.3%)	93 (93.0%)
Censored	14 (14.7%)	7 (7.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (1.4, 2.0)	1.4 (0.8, 2.1)
50%	2.8 (2.1, 3.7)	3.5 (2.3, 5.9)
75%	8.0 (4.8, 13.2)	15.8 (10.2, 20.8)
Survival probability (95% CI) at		
Month 6	30.4% (21.3%, 40.1%)	39.8% (30.1%, 49.3%)
Month 12	19.1% (11.5%, 28.1%)	29.6% (20.9%, 38.8%)
Month 18	14.7% (8.0%, 23.4%)	20.4% (13.1%, 28.9%)
Month 24	10.3% (4.7%, 18.3%)	12.2% (6.7%, 19.6%)
Month 30	5.9% (2.0%, 12.9%)	11.2% (6.0%, 18.4%)
Month 36	5.9% (2.0%, 12.9%)	6.7% (2.8%, 13.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.15 (0.846, 1.561)	
p-value of 2-sided stratified log-rank test	0.3670	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	81	93
0	47 (58.0%)	60 (64.5%)
1	13 (16.0%)	10 (10.8%)
2	6 (7.4%)	5 (5.4%)
3	4 (4.9%)	4 (4.3%)
>=4	11 (13.6%)	14 (15.1%)
p-value from Interaction Test[c]	0.5766	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	26 (26.8%)	14 (16.7%)
Censored	71 (73.2%)	70 (83.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	16.9 (1.5, NE)	NE (2.2, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	75.4% (65.3%, 82.9%)	81.8% (71.2%, 88.8%)
Month 12	75.4% (65.3%, 82.9%)	81.8% (71.2%, 88.8%)
Month 18	73.6% (63.1%, 81.6%)	81.8% (71.2%, 88.8%)
Month 24	69.7% (58.3%, 78.6%)	81.8% (71.2%, 88.8%)
Month 30	69.7% (58.3%, 78.6%)	81.8% (71.2%, 88.8%)
Month 36	69.7% (58.3%, 78.6%)	81.8% (71.2%, 88.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.64 (0.332, 1.222)	
p-value of 2-sided stratified log-rank test	0.1741	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	26	14
0	10 (38.5%)	9 (64.3%)
1	7 (26.9%)	3 (21.4%)
2	2 (7.7%)	0
3	0	0
>=4	7 (26.9%)	2 (14.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	28 (29.5%)	26 (26.0%)
Censored	67 (70.5%)	74 (74.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, NE)	8.3 (1.0, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	70.5% (59.8%, 78.9%)	75.8% (65.9%, 83.3%)
Month 12	70.5% (59.8%, 78.9%)	72.9% (62.5%, 80.9%)
Month 18	68.6% (57.4%, 77.4%)	71.1% (60.1%, 79.5%)
Month 24	66.1% (54.2%, 75.6%)	71.1% (60.1%, 79.5%)
Month 30	66.1% (54.2%, 75.6%)	71.1% (60.1%, 79.5%)
Month 36	66.1% (54.2%, 75.6%)	71.1% (60.1%, 79.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.82 (0.481, 1.406)	
p-value of 2-sided stratified log-rank test	0.4717	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	28	26
0	9 (32.1%)	9 (34.6%)
1	10 (35.7%)	2 (7.7%)
2	1 (3.6%)	3 (11.5%)
3	1 (3.6%)	3 (11.5%)
>=4	7 (25.0%)	9 (34.6%)
p-value from Interaction Test[c]	0.6149	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	51 (52.6%)	44 (52.4%)
Censored	46 (47.4%)	40 (47.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.1)	1.4 (0.9, 2.2)
50%	10.3 (2.9, NE)	12.9 (2.8, 32.3)
75%	NE (35.4, NE)	NE (32.3, NE)
Survival probability (95% CI) at		
Month 6	54.8% (44.0%, 64.3%)	53.7% (42.0%, 64.1%)
Month 12	47.2% (36.2%, 57.5%)	52.3% (40.5%, 62.7%)
Month 18	43.9% (32.8%, 54.4%)	48.5% (36.6%, 59.4%)
Month 24	41.9% (30.7%, 52.7%)	41.3% (28.8%, 53.3%)
Month 30	41.9% (30.7%, 52.7%)	38.3% (25.7%, 50.8%)
Month 36	36.6% (23.3%, 50.0%)	34.8% (21.9%, 48.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.92 (0.614, 1.390)	
p-value of 2-sided stratified log-rank test	0.6971	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	51	44
0	29 (56.9%)	26 (59.1%)
1	12 (23.5%)	8 (18.2%)
2	3 (5.9%)	5 (11.4%)
3	2 (3.9%)	1 (2.3%)
>=4	5 (9.8%)	4 (9.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	49 (51.6%)	51 (51.0%)
Censored	46 (48.4%)	49 (49.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (1.4, 2.2)	2.1 (1.4, 2.5)
50%	4.7 (2.8, 29.4)	10.2 (3.7, 37.4)
75%	NE (NE, NE)	NE (37.4, NE)
Survival probability (95% CI) at		
Month 6	49.8% (38.8%, 59.9%)	57.5% (46.8%, 66.8%)
Month 12	45.3% (34.2%, 55.7%)	48.6% (37.5%, 58.8%)
Month 18	43.6% (32.5%, 54.1%)	45.0% (33.8%, 55.6%)
Month 24	43.6% (32.5%, 54.1%)	42.8% (31.3%, 53.7%)
Month 30	37.8% (25.8%, 49.6%)	40.2% (28.6%, 51.6%)
Month 36	37.8% (25.8%, 49.6%)	40.2% (28.6%, 51.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.11 (0.743, 1.653)	
p-value of 2-sided stratified log-rank test	0.6093	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	49	51
0	33 (67.3%)	30 (58.8%)
1	8 (16.3%)	3 (5.9%)
2	4 (8.2%)	4 (7.8%)
3	1 (2.0%)	5 (9.8%)
>=4	3 (6.1%)	9 (17.6%)
p-value from Interaction Test[c]	0.6859	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	72 (74.2%)	64 (76.2%)
Censored	25 (25.8%)	20 (23.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.2)	1.4 (0.9, 2.2)
50%	6.1 (2.9, 10.3)	6.0 (2.8, 13.4)
75%	29.8 (14.6, NE)	24.6 (18.2, NE)
Survival probability (95% CI) at		
Month 6	51.3% (40.7%, 60.8%)	50.7% (39.3%, 60.9%)
Month 12	37.3% (27.4%, 47.2%)	46.7% (35.5%, 57.1%)
Month 18	32.4% (23.0%, 42.2%)	37.4% (26.8%, 47.9%)
Month 24	28.7% (19.6%, 38.4%)	26.0% (16.7%, 36.2%)
Month 30	24.9% (16.4%, 34.5%)	20.0% (11.7%, 29.9%)
Month 36	20.3% (11.7%, 30.5%)	13.7% (5.5%, 25.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.91 (0.644, 1.288)	
p-value of 2-sided stratified log-rank test	0.5877	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	72	64
0	50 (69.4%)	46 (71.9%)
1	12 (16.7%)	8 (12.5%)
2	3 (4.2%)	5 (7.8%)
3	2 (2.8%)	1 (1.6%)
>=4	5 (6.9%)	4 (6.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	71 (74.7%)	85 (85.0%)
Censored	24 (25.3%)	15 (15.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (1.1, 2.1)	2.1 (1.4, 2.8)
50%	4.4 (2.6, 12.4)	8.6 (4.1, 12.2)
75%	24.6 (19.2, NE)	21.7 (15.0, 34.7)
Survival probability (95% CI) at		
Month 6	47.3% (36.8%, 57.1%)	56.0% (45.6%, 65.2%)
Month 12	40.2% (30.0%, 50.2%)	41.0% (31.1%, 50.6%)
Month 18	35.0% (25.2%, 45.0%)	30.2% (21.3%, 39.6%)
Month 24	25.6% (16.7%, 35.4%)	22.7% (14.8%, 31.5%)
Month 30	18.9% (11.1%, 28.1%)	19.3% (12.0%, 27.8%)
Month 36	17.3% (9.8%, 26.5%)	15.3% (8.7%, 23.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.99 (0.720, 1.368)	
p-value of 2-sided stratified log-rank test	0.9728	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	71	85
0	55 (77.5%)	64 (75.3%)
1	8 (11.3%)	3 (3.5%)
2	4 (5.6%)	4 (4.7%)
3	1 (1.4%)	5 (5.9%)
>=4	3 (4.2%)	9 (10.6%)
p-value from Interaction Test[c]	0.8474	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	35 (36.1%)	26 (31.0%)
Censored	62 (63.9%)	58 (69.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.4, 8.5)	3.0 (1.4, NE)
50%	NE (23.8, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	66.8% (56.2%, 75.4%)	70.5% (59.0%, 79.3%)
Month 12	62.3% (51.2%, 71.6%)	65.7% (53.7%, 75.3%)
Month 18	62.3% (51.2%, 71.6%)	65.7% (53.7%, 75.3%)
Month 24	60.3% (48.9%, 70.0%)	65.7% (53.7%, 75.3%)
Month 30	60.3% (48.9%, 70.0%)	65.7% (53.7%, 75.3%)
Month 36	60.3% (48.9%, 70.0%)	65.7% (53.7%, 75.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.91 (0.549, 1.521)	
p-value of 2-sided stratified log-rank test	0.7210	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	35	26
0	18 (51.4%)	15 (57.7%)
1	5 (14.3%)	2 (7.7%)
2	2 (5.7%)	5 (19.2%)
3	4 (11.4%)	0
>=4	6 (17.1%)	4 (15.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	41 (43.2%)	38 (38.0%)
Censored	54 (56.8%)	62 (62.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.4 (1.5, 3.5)	1.6 (1.0, 6.9)
50%	16.9 (5.7, NE)	NE (10.9, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	61.2% (49.9%, 70.7%)	66.6% (56.2%, 75.1%)
Month 12	51.9% (40.2%, 62.4%)	60.5% (49.3%, 69.9%)
Month 18	49.9% (38.0%, 60.7%)	58.7% (47.4%, 68.5%)
Month 24	47.6% (35.5%, 58.7%)	56.3% (44.4%, 66.6%)
Month 30	47.6% (35.5%, 58.7%)	56.3% (44.4%, 66.6%)
Month 36	47.6% (35.5%, 58.7%)	56.3% (44.4%, 66.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.90 (0.572, 1.401)	
p-value of 2-sided stratified log-rank test	0.6161	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	41	38
0	25 (61.0%)	18 (47.4%)
1	4 (9.8%)	2 (5.3%)
2	2 (4.9%)	6 (15.8%)
3	4 (9.8%)	1 (2.6%)
>=4	6 (14.6%)	11 (28.9%)
p-value from Interaction Test[c]	0.9509	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	43 (44.3%)	41 (48.8%)
Censored	54 (55.7%)	43 (51.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.6 (1.4, 7.3)	2.4 (1.4, 4.5)
50%	30.1 (11.4, NE)	15.9 (7.0, 34.5)
75%	NE (NE, NE)	NE (34.5, NE)
Survival probability (95% CI) at		
Month 6	70.1% (59.7%, 78.3%)	65.5% (53.8%, 74.9%)
Month 12	60.1% (48.8%, 69.7%)	54.6% (42.5%, 65.3%)
Month 18	58.5% (47.0%, 68.3%)	48.8% (36.4%, 60.1%)
Month 24	52.7% (40.6%, 63.4%)	48.8% (36.4%, 60.1%)
Month 30	50.6% (38.3%, 61.6%)	43.5% (30.6%, 55.7%)
Month 36	41.6% (28.1%, 54.5%)	35.5% (21.4%, 49.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.90 (0.580, 1.388)	
p-value of 2-sided stratified log-rank test	0.6281	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	43	41
0	28 (65.1%)	31 (75.6%)
1	8 (18.6%)	2 (4.9%)
2	3 (7.0%)	4 (9.8%)
3	2 (4.7%)	2 (4.9%)
>=4	2 (4.7%)	2 (4.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	56 (58.9%)	50 (50.0%)
Censored	39 (41.1%)	50 (50.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.9, 3.0)	1.9 (1.4, 3.3)
50%	6.6 (3.7, 13.8)	15.3 (3.8, NE)
75%	41.0 (19.4, NE)	NE (38.2, NE)
Survival probability (95% CI) at		
Month 6	51.0% (39.9%, 61.0%)	57.6% (47.0%, 66.9%)
Month 12	40.9% (30.0%, 51.5%)	50.6% (39.7%, 60.6%)
Month 18	39.3% (28.4%, 50.0%)	47.1% (36.0%, 57.5%)
Month 24	32.5% (21.5%, 43.9%)	47.1% (36.0%, 57.5%)
Month 30	29.8% (18.8%, 41.6%)	42.4% (30.7%, 53.6%)
Month 36	27.1% (16.2%, 39.1%)	42.4% (30.7%, 53.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.26 (0.852, 1.863)	
p-value of 2-sided stratified log-rank test	0.2424	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	56	50
0	36 (64.3%)	33 (66.0%)
1	13 (23.2%)	10 (20.0%)
2	2 (3.6%)	1 (2.0%)
3	1 (1.8%)	3 (6.0%)
>=4	4 (7.1%)	3 (6.0%)
p-value from Interaction Test[c]	0.2537	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	70 (72.2%)	62 (73.8%)
Censored	27 (27.8%)	22 (26.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.6 (1.4, 6.0)	2.4 (1.4, 3.5)
50%	9.5 (7.3, 19.5)	12.6 (6.5, 16.1)
75%	31.2 (25.3, NE)	29.4 (18.2, NE)
Survival probability (95% CI) at		
Month 6	66.3% (55.8%, 74.8%)	61.8% (50.4%, 71.4%)
Month 12	47.2% (36.7%, 57.0%)	50.1% (38.7%, 60.4%)
Month 18	41.3% (31.0%, 51.2%)	35.5% (25.1%, 46.1%)
Month 24	36.1% (26.2%, 46.1%)	29.9% (20.1%, 40.3%)
Month 30	28.4% (19.2%, 38.2%)	24.2% (15.2%, 34.3%)
Month 36	20.6% (12.4%, 30.4%)	20.1% (11.5%, 30.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.97 (0.685, 1.373)	
p-value of 2-sided stratified log-rank test	0.8677	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	70	62
0	55 (78.6%)	52 (83.9%)
1	8 (11.4%)	2 (3.2%)
2	3 (4.3%)	4 (6.5%)
3	2 (2.9%)	2 (3.2%)
>=4	2 (2.9%)	2 (3.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	74 (77.9%)	85 (85.0%)
Censored	21 (22.1%)	15 (15.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.7 (1.0, 2.8)	2.0 (1.4, 3.3)
50%	5.5 (3.1, 11.8)	9.4 (3.8, 12.2)
75%	20.1 (13.4, 27.8)	25.0 (17.3, 34.7)
Survival probability (95% CI) at		
Month 6	49.2% (38.5%, 59.0%)	57.1% (46.7%, 66.2%)
Month 12	39.7% (29.4%, 49.7%)	41.2% (31.4%, 50.8%)
Month 18	30.9% (21.5%, 40.8%)	33.8% (24.6%, 43.3%)
Month 24	22.5% (14.1%, 32.2%)	25.2% (17.0%, 34.3%)
Month 30	15.5% (8.5%, 24.5%)	20.8% (13.3%, 29.5%)
Month 36	14.1% (7.4%, 22.9%)	15.4% (8.7%, 23.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.08 (0.781, 1.483)	
p-value of 2-sided stratified log-rank test	0.6508	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	74	85
0	54 (73.0%)	68 (80.0%)
1	13 (17.6%)	10 (11.8%)
2	2 (2.7%)	1 (1.2%)
3	1 (1.4%)	3 (3.5%)
>=4	4 (5.4%)	3 (3.5%)
p-value from Interaction Test[c]	0.7152	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	46 (47.4%)	27 (32.1%)
Censored	51 (52.6%)	57 (67.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 3.0)	3.0 (1.4, 7.2)
50%	22.5 (4.1, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	57.3% (46.6%, 66.6%)	69.2% (57.6%, 78.2%)
Month 12	54.6% (43.8%, 64.2%)	64.6% (52.6%, 74.3%)
Month 18	51.3% (40.2%, 61.3%)	64.6% (52.6%, 74.3%)
Month 24	49.1% (37.8%, 59.5%)	64.6% (52.6%, 74.3%)
Month 30	49.1% (37.8%, 59.5%)	64.6% (52.6%, 74.3%)
Month 36	46.4% (34.6%, 57.4%)	64.6% (52.6%, 74.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.67 (0.413, 1.079)	
p-value of 2-sided stratified log-rank test	0.0934	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	46	27
0	17 (37.0%)	11 (40.7%)
1	8 (17.4%)	6 (22.2%)
2	2 (4.3%)	4 (14.8%)
3	0	1 (3.7%)
>=4	19 (41.3%)	5 (18.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	30 (31.6%)	37 (37.0%)
Censored	65 (68.4%)	63 (63.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.7 (0.9, 7.2)	2.1 (1.2, 7.6)
50%	NE (NE, NE)	NE (15.3, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	68.8% (57.8%, 77.4%)	67.5% (57.1%, 76.0%)
Month 12	64.2% (52.8%, 73.6%)	63.1% (52.1%, 72.2%)
Month 18	64.2% (52.8%, 73.6%)	61.1% (49.8%, 70.6%)
Month 24	64.2% (52.8%, 73.6%)	56.5% (44.2%, 67.0%)
Month 30	64.2% (52.8%, 73.6%)	56.5% (44.2%, 67.0%)
Month 36	64.2% (52.8%, 73.6%)	56.5% (44.2%, 67.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.19 (0.731, 1.938)	
p-value of 2-sided stratified log-rank test	0.4930	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	30	37
0	11 (36.7%)	17 (45.9%)
1	3 (10.0%)	9 (24.3%)
2	3 (10.0%)	2 (5.4%)
3	4 (13.3%)	1 (2.7%)
>=4	9 (30.0%)	8 (21.6%)
p-value from Interaction Test[c]	0.1284	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	71 (73.2%)	55 (65.5%)
Censored	26 (26.8%)	29 (34.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.8)	0.7 (0.7, 0.9)
50%	1.3 (0.9, 1.6)	1.4 (1.0, 2.8)
75%	22.5 (3.5, NE)	NE (11.3, NE)
Survival probability (95% CI) at		
Month 6	27.6% (18.9%, 36.9%)	37.2% (26.7%, 47.8%)
Month 12	26.0% (17.4%, 35.5%)	33.7% (23.3%, 44.5%)
Month 18	26.0% (17.4%, 35.5%)	27.8% (17.7%, 38.9%)
Month 24	24.3% (15.8%, 33.8%)	27.8% (17.7%, 38.9%)
Month 30	22.4% (14.0%, 32.0%)	27.8% (17.7%, 38.9%)
Month 36	22.4% (14.0%, 32.0%)	27.8% (17.7%, 38.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.16 (0.814, 1.661)	
p-value of 2-sided stratified log-rank test	0.3844	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	71	55
0	29 (40.8%)	19 (34.5%)
1	9 (12.7%)	8 (14.5%)
2	3 (4.2%)	8 (14.5%)
3	4 (5.6%)	4 (7.3%)
>=4	26 (36.6%)	16 (29.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	71 (74.7%)	64 (64.0%)
Censored	24 (25.3%)	36 (36.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.8)	0.8 (0.7, 0.9)
50%	1.4 (0.9, 1.8)	2.1 (1.3, 3.6)
75%	6.1 (2.4, 28.5)	NE (20.6, NE)
Survival probability (95% CI) at		
Month 6	26.1% (17.3%, 35.7%)	38.3% (28.6%, 47.9%)
Month 12	21.9% (13.7%, 31.3%)	38.3% (28.6%, 47.9%)
Month 18	18.4% (10.6%, 27.8%)	36.7% (26.9%, 46.5%)
Month 24	16.3% (8.8%, 25.8%)	33.0% (23.2%, 43.2%)
Month 30	13.6% (6.4%, 23.5%)	31.1% (21.2%, 41.4%)
Month 36	13.6% (6.4%, 23.5%)	27.6% (17.2%, 39.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.30 (0.918, 1.839)	
p-value of 2-sided stratified log-rank test	0.1321	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	71	64
0	33 (46.5%)	27 (42.2%)
1	10 (14.1%)	5 (7.8%)
2	4 (5.6%)	4 (6.3%)
3	2 (2.8%)	3 (4.7%)
>=4	22 (31.0%)	25 (39.1%)
p-value from Interaction Test[c]	0.6279	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	86 (88.7%)	68 (81.0%)
Censored	11 (11.3%)	16 (19.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.7 (0.7, 0.9)
50%	1.4 (0.9, 2.1)	1.4 (0.9, 2.8)
75%	6.1 (3.5, 22.5)	16.7 (4.2, 28.2)
Survival probability (95% CI) at		
Month 6	25.7% (17.4%, 34.8%)	33.6% (23.6%, 43.9%)
Month 12	20.1% (12.7%, 28.8%)	29.7% (20.2%, 39.9%)
Month 18	17.9% (10.9%, 26.3%)	19.2% (11.3%, 28.6%)
Month 24	15.6% (9.1%, 23.8%)	17.8% (10.3%, 27.0%)
Month 30	10.1% (5.0%, 17.2%)	14.8% (7.9%, 23.8%)
Month 36	10.1% (5.0%, 17.2%)	14.8% (7.9%, 23.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.12 (0.814, 1.555)	
p-value of 2-sided stratified log-rank test	0.4564	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	86	68
0	44 (51.2%)	32 (47.1%)
1	9 (10.5%)	8 (11.8%)
2	3 (3.5%)	8 (11.8%)
3	4 (4.7%)	4 (5.9%)
>=4	26 (30.2%)	16 (23.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	82 (86.3%)	86 (86.0%)
Censored	13 (13.7%)	14 (14.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.8)	0.8 (0.7, 0.9)
50%	1.4 (0.9, 1.8)	2.1 (1.3, 4.1)
75%	6.1 (2.4, 18.0)	18.1 (9.4, 31.3)
Survival probability (95% CI) at		
Month 6	25.3% (16.9%, 34.6%)	37.8% (28.2%, 47.2%)
Month 12	19.1% (11.6%, 27.9%)	31.6% (22.7%, 40.9%)
Month 18	16.4% (9.4%, 25.0%)	25.5% (17.4%, 34.4%)
Month 24	12.3% (6.3%, 20.4%)	18.2% (11.3%, 26.4%)
Month 30	6.8% (2.6%, 13.9%)	17.1% (10.4%, 25.2%)
Month 36	6.8% (2.6%, 13.9%)	12.4% (6.5%, 20.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.25 (0.911, 1.709)	
p-value of 2-sided stratified log-rank test	0.1626	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	82	86
0	44 (53.7%)	49 (57.0%)
1	10 (12.2%)	5 (5.8%)
2	4 (4.9%)	4 (4.7%)
3	2 (2.4%)	3 (3.5%)
>=4	22 (26.8%)	25 (29.1%)
p-value from Interaction Test[c]	0.7914	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	22 (22.7%)	25 (29.8%)
Censored	75 (77.3%)	59 (70.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	21.8 (12.9, NE)	7.2 (1.5, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	86.1% (77.2%, 91.7%)	76.9% (65.8%, 84.8%)
Month 12	84.6% (75.2%, 90.6%)	69.4% (57.5%, 78.6%)
Month 18	79.9% (69.4%, 87.2%)	67.3% (55.0%, 76.9%)
Month 24	74.3% (62.4%, 82.9%)	65.0% (52.2%, 75.1%)
Month 30	71.9% (59.3%, 81.2%)	65.0% (52.2%, 75.1%)
Month 36	68.5% (54.5%, 79.0%)	65.0% (52.2%, 75.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.56 (0.877, 2.774)	
p-value of 2-sided stratified log-rank test	0.1302	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	22	25
0	10 (45.5%)	12 (48.0%)
1	3 (13.6%)	2 (8.0%)
2	3 (13.6%)	1 (4.0%)
3	2 (9.1%)	3 (12.0%)
>=4	4 (18.2%)	7 (28.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	23 (24.2%)	21 (21.0%)
Censored	72 (75.8%)	79 (79.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	13.6 (2.1, NE)	NE (2.3, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	78.8% (68.4%, 86.1%)	79.9% (70.2%, 86.7%)
Month 12	77.3% (66.7%, 84.9%)	76.7% (66.3%, 84.3%)
Month 18	71.9% (60.1%, 80.7%)	76.7% (66.3%, 84.3%)
Month 24	69.7% (57.4%, 79.1%)	76.7% (66.3%, 84.3%)
Month 30	69.7% (57.4%, 79.1%)	76.7% (66.3%, 84.3%)
Month 36	69.7% (57.4%, 79.1%)	76.7% (66.3%, 84.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.80 (0.439, 1.449)	
p-value of 2-sided stratified log-rank test	0.4556	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	23	21
0	11 (47.8%)	12 (57.1%)
1	5 (21.7%)	4 (19.0%)
2	3 (13.0%)	2 (9.5%)
3	0	1 (4.8%)
>=4	4 (17.4%)	2 (9.5%)
p-value from Interaction Test[c]	0.1070	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	10 (10.3%)	9 (10.7%)
Censored	87 (89.7%)	75 (89.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (1.4, NE)	NE (5.3, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	83.2% (70.2%, 90.9%)	86.8% (72.8%, 93.9%)
Month 12	80.7% (66.9%, 89.2%)	78.0% (61.5%, 88.1%)
Month 18	80.7% (66.9%, 89.2%)	78.0% (61.5%, 88.1%)
Month 24	80.7% (66.9%, 89.2%)	78.0% (61.5%, 88.1%)
Month 30	80.7% (66.9%, 89.2%)	78.0% (61.5%, 88.1%)
Month 36	80.7% (66.9%, 89.2%)	78.0% (61.5%, 88.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.95 (0.381, 2.382)	
p-value of 2-sided stratified log-rank test	0.9174	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	10	9
0	2 (20.0%)	3 (33.3%)
1	5 (50.0%)	3 (33.3%)
2	2 (20.0%)	1 (11.1%)
3	0	1 (11.1%)
>=4	1 (10.0%)	1 (11.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	7 (7.4%)	4 (4.0%)
Censored	88 (92.6%)	96 (96.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (2.8, NE)	NE (3.6, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	85.7% (69.0%, 93.8%)	86.9% (68.5%, 95.0%)
Month 12	78.6% (59.9%, 89.3%)	86.9% (68.5%, 95.0%)
Month 18	78.6% (59.9%, 89.3%)	86.9% (68.5%, 95.0%)
Month 24	78.6% (59.9%, 89.3%)	86.9% (68.5%, 95.0%)
Month 30	78.6% (59.9%, 89.3%)	86.9% (68.5%, 95.0%)
Month 36	78.6% (59.9%, 89.3%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.54 (0.435, 5.451)	
p-value of 2-sided stratified log-rank test	0.5008	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	7	4
0	5 (71.4%)	4 (100%)
1	1 (14.3%)	0
2	0	0
3	1 (14.3%)	0
>=4	0	0
p-value from Interaction Test[c]	0.5834	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	48 (49.5%)	44 (52.4%)
Censored	49 (50.5%)	40 (47.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	8.0 (5.0, 11.0)	8.8 (4.2, 12.8)
50%	25.8 (13.2, 29.8)	16.3 (12.8, 22.2)
75%	40.6 (29.8, NE)	35.5 (19.8, NE)
Survival probability (95% CI) at		
Month 6	81.9% (71.3%, 88.9%)	79.7% (67.6%, 87.7%)
Month 12	64.8% (52.7%, 74.6%)	66.3% (53.0%, 76.6%)
Month 18	58.6% (46.2%, 69.0%)	43.8% (30.6%, 56.2%)
Month 24	53.6% (41.1%, 64.5%)	35.4% (23.0%, 48.1%)
Month 30	35.2% (23.4%, 47.2%)	26.7% (15.4%, 39.3%)
Month 36	27.9% (16.7%, 40.3%)	21.4% (11.0%, 34.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.85 (0.556, 1.297)	
p-value of 2-sided stratified log-rank test	0.4484	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	48	44
0	40 (83.3%)	38 (86.4%)
1	5 (10.4%)	3 (6.8%)
2	2 (4.2%)	1 (2.3%)
3	0	1 (2.3%)
>=4	1 (2.1%)	1 (2.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	46 (48.4%)	67 (67.0%)
Censored	49 (51.6%)	33 (33.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	8.0 (5.6, 13.4)	10.2 (8.8, 12.9)
50%	20.1 (13.4, 24.6)	17.3 (14.7, 21.5)
75%	30.7 (24.6, 37.6)	29.3 (22.0, 36.1)
Survival probability (95% CI) at		
Month 6	83.0% (71.4%, 90.2%)	89.9% (80.9%, 94.8%)
Month 12	69.8% (56.8%, 79.6%)	68.7% (57.1%, 77.9%)
Month 18	59.3% (45.9%, 70.5%)	48.2% (36.5%, 58.9%)
Month 24	42.2% (29.2%, 54.6%)	31.4% (21.2%, 42.2%)
Month 30	29.4% (17.7%, 42.0%)	23.8% (14.7%, 34.2%)
Month 36	17.6% (7.9%, 30.5%)	15.2% (7.7%, 25.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.97 (0.656, 1.446)	
p-value of 2-sided stratified log-rank test	0.9011	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	46	67
0	44 (95.7%)	67 (100%)
1	1 (2.2%)	0
2	0	0
3	1 (2.2%)	0
>=4	0	0
p-value from Interaction Test[c]	0.6544	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	8 (8.2%)	3 (3.6%)
Censored	89 (91.8%)	81 (96.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (8.3, NE)	NE (27.7, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	90.4% (78.3%, 95.9%)	95.7% (83.8%, 98.9%)
Month 12	82.8% (68.3%, 91.1%)	95.7% (83.8%, 98.9%)
Month 18	82.8% (68.3%, 91.1%)	95.7% (83.8%, 98.9%)
Month 24	82.8% (68.3%, 91.1%)	95.7% (83.8%, 98.9%)
Month 30	82.8% (68.3%, 91.1%)	87.7% (59.3%, 96.8%)
Month 36	82.8% (68.3%, 91.1%)	87.7% (59.3%, 96.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.46 (0.121, 1.724)	
p-value of 2-sided stratified log-rank test	0.2309	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	8	3
0	3 (37.5%)	1 (33.3%)
1	2 (25.0%)	1 (33.3%)
2	3 (37.5%)	0
3	0	0
>=4	0	1 (33.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	3 (3.2%)	4 (4.0%)
Censored	92 (96.8%)	96 (96.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (13.9, NE)	NE (25.1, NE)
50%	NE (NE, NE)	NE (25.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	93.9% (77.5%, 98.4%)	91.3% (75.3%, 97.1%)
Month 12	93.9% (77.5%, 98.4%)	91.3% (75.3%, 97.1%)
Month 18	88.7% (67.5%, 96.4%)	91.3% (75.3%, 97.1%)
Month 24	88.7% (67.5%, 96.4%)	91.3% (75.3%, 97.1%)
Month 30	88.7% (67.5%, 96.4%)	79.8% (45.5%, 93.8%)
Month 36	88.7% (67.5%, 96.4%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.81 (0.354, 9.291)	
p-value of 2-sided stratified log-rank test	0.4715	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	3	4
0	1 (33.3%)	3 (75.0%)
1	0	0
2	0	0
3	1 (33.3%)	0
>=4	1 (33.3%)	1 (25.0%)
p-value from Interaction Test[c]	0.1235	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	55 (56.7%)	44 (52.4%)
Censored	42 (43.3%)	40 (47.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (0.9, 3.7)	2.3 (1.7, 4.6)
50%	10.1 (5.3, 21.8)	15.2 (7.2, 31.3)
75%	NE (23.1, NE)	NE (31.3, NE)
Survival probability (95% CI) at		
Month 6	57.9% (47.1%, 67.2%)	62.4% (50.5%, 72.2%)
Month 12	46.9% (36.0%, 57.2%)	56.1% (44.0%, 66.6%)
Month 18	45.3% (34.3%, 55.7%)	44.8% (32.4%, 56.5%)
Month 24	35.0% (24.2%, 46.0%)	42.3% (29.8%, 54.3%)
Month 30	35.0% (24.2%, 46.0%)	39.7% (27.0%, 52.0%)
Month 36	35.0% (24.2%, 46.0%)	30.5% (18.0%, 44.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.18 (0.785, 1.778)	
p-value of 2-sided stratified log-rank test	0.4175	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	55	44
0	36 (65.5%)	37 (84.1%)
1	4 (7.3%)	3 (6.8%)
2	6 (10.9%)	1 (2.3%)
3	5 (9.1%)	1 (2.3%)
>=4	4 (7.3%)	2 (4.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	44 (46.3%)	58 (58.0%)
Censored	51 (53.7%)	42 (42.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.3 (0.9, 5.6)	2.8 (1.4, 4.2)
50%	15.6 (6.9, NE)	13.4 (6.9, 20.8)
75%	NE (NE, NE)	34.3 (25.6, NE)
Survival probability (95% CI) at		
Month 6	62.9% (51.7%, 72.2%)	60.8% (50.2%, 69.9%)
Month 12	55.6% (44.1%, 65.7%)	51.5% (40.6%, 61.4%)
Month 18	47.5% (35.8%, 58.3%)	43.9% (32.8%, 54.4%)
Month 24	47.5% (35.8%, 58.3%)	36.2% (25.1%, 47.4%)
Month 30	45.3% (33.5%, 56.4%)	31.7% (20.7%, 43.2%)
Month 36	45.3% (33.5%, 56.4%)	23.8% (12.3%, 37.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.80 (0.534, 1.194)	
p-value of 2-sided stratified log-rank test	0.2681	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	44	58
0	27 (61.4%)	30 (51.7%)
1	8 (18.2%)	15 (25.9%)
2	0	3 (5.2%)
3	3 (6.8%)	4 (6.9%)
>=4	6 (13.6%)	6 (10.3%)
p-value from Interaction Test[c]	0.1784	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	76 (78.4%)	64 (76.2%)
Censored	21 (21.6%)	20 (23.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (0.9, 4.3)	2.3 (1.5, 4.3)
50%	6.9 (5.2, 9.5)	12.6 (5.4, 16.0)
75%	25.8 (13.2, NE)	27.2 (17.1, NE)
Survival probability (95% CI) at		
Month 6	54.9% (44.4%, 64.3%)	58.1% (46.6%, 67.9%)
Month 12	36.7% (27.0%, 46.3%)	50.2% (38.7%, 60.5%)
Month 18	32.1% (22.9%, 41.7%)	31.5% (21.5%, 42.0%)
Month 24	25.2% (16.8%, 34.4%)	27.3% (17.8%, 37.6%)
Month 30	22.9% (14.9%, 32.0%)	21.4% (12.9%, 31.4%)
Month 36	19.6% (11.9%, 28.7%)	16.5% (8.9%, 26.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.13 (0.806, 1.593)	
p-value of 2-sided stratified log-rank test	0.4664	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	76	64
0	57 (75.0%)	57 (89.1%)
1	4 (5.3%)	3 (4.7%)
2	6 (7.9%)	1 (1.6%)
3	5 (6.6%)	1 (1.6%)
>=4	4 (5.3%)	2 (3.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	69 (72.6%)	86 (86.0%)
Censored	26 (27.4%)	14 (14.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.9, 2.9)	2.8 (1.4, 4.2)
50%	9.6 (5.7, 17.6)	9.8 (6.0, 14.8)
75%	30.7 (20.3, NE)	21.7 (17.3, 32.4)
Survival probability (95% CI) at		
Month 6	58.0% (47.1%, 67.4%)	61.2% (50.8%, 70.1%)
Month 12	48.2% (37.4%, 58.2%)	45.7% (35.6%, 55.2%)
Month 18	39.3% (28.9%, 49.5%)	33.0% (23.9%, 42.4%)
Month 24	31.7% (22.0%, 41.8%)	21.1% (13.6%, 29.8%)
Month 30	26.6% (17.6%, 36.5%)	17.6% (10.6%, 26.0%)
Month 36	21.1% (12.9%, 30.7%)	11.0% (5.2%, 19.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.87 (0.626, 1.200)	
p-value of 2-sided stratified log-rank test	0.3876	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	69	86
0	52 (75.4%)	58 (67.4%)
1	8 (11.6%)	15 (17.4%)
2	0	3 (3.5%)
3	3 (4.3%)	4 (4.7%)
>=4	6 (8.7%)	6 (7.0%)
p-value from Interaction Test[c]	0.2693	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	47 (48.5%)	42 (50.0%)
Censored	50 (51.5%)	42 (50.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 1.7)	0.8 (0.7, 1.4)
50%	20.2 (2.6, NE)	3.6 (1.4, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	53.1% (42.4%, 62.6%)	46.3% (34.9%, 57.0%)
Month 12	51.7% (41.0%, 61.3%)	46.3% (34.9%, 57.0%)
Month 18	50.1% (39.3%, 59.9%)	46.3% (34.9%, 57.0%)
Month 24	48.3% (37.4%, 58.4%)	46.3% (34.9%, 57.0%)
Month 30	48.3% (37.4%, 58.4%)	46.3% (34.9%, 57.0%)
Month 36	48.3% (37.4%, 58.4%)	46.3% (34.9%, 57.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.17 (0.770, 1.792)	
p-value of 2-sided stratified log-rank test	0.4800	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	47	42
0	17 (36.2%)	11 (26.2%)
1	8 (17.0%)	11 (26.2%)
2	3 (6.4%)	1 (2.4%)
3	5 (10.6%)	5 (11.9%)
>=4	14 (29.8%)	14 (33.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	47 (49.5%)	33 (33.0%)
Censored	48 (50.5%)	67 (67.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.6 (1.0, 6.9)
50%	4.1 (2.1, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	49.2% (38.3%, 59.3%)	66.8% (56.5%, 75.2%)
Month 12	49.2% (38.3%, 59.3%)	65.6% (55.1%, 74.2%)
Month 18	45.4% (34.1%, 56.0%)	65.6% (55.1%, 74.2%)
Month 24	42.8% (31.3%, 53.9%)	65.6% (55.1%, 74.2%)
Month 30	42.8% (31.3%, 53.9%)	65.6% (55.1%, 74.2%)
Month 36	42.8% (31.3%, 53.9%)	65.6% (55.1%, 74.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.58 (0.371, 0.911)	
p-value of 2-sided stratified log-rank test	0.0163	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	47	33
0	11 (23.4%)	10 (30.3%)
1	10 (21.3%)	3 (9.1%)
2	2 (4.3%)	4 (12.1%)
3	7 (14.9%)	3 (9.1%)
>=4	17 (36.2%)	13 (39.4%)
p-value from Interaction Test[c]	0.0166	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	78 (80.4%)	64 (76.2%)
Censored	19 (19.6%)	20 (23.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	0.9 (0.7, 1.4)
50%	2.1 (1.4, 2.3)	1.5 (1.4, 2.8)
75%	4.2 (2.8, NE)	5.8 (3.5, NE)
Survival probability (95% CI) at		
Month 6	22.1% (14.4%, 30.9%)	23.7% (14.9%, 33.6%)
Month 12	16.9% (9.9%, 25.3%)	17.9% (9.9%, 27.9%)
Month 18	16.9% (9.9%, 25.3%)	17.9% (9.9%, 27.9%)
Month 24	16.9% (9.9%, 25.3%)	14.3% (6.4%, 25.3%)
Month 30	16.9% (9.9%, 25.3%)	14.3% (6.4%, 25.3%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.02 (0.726, 1.438)	
p-value of 2-sided stratified log-rank test	0.9047	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	78	64
0	18 (23.1%)	25 (39.1%)
1	4 (5.1%)	2 (3.1%)
2	10 (12.8%)	5 (7.8%)
3	4 (5.1%)	4 (6.3%)
>=4	42 (53.8%)	28 (43.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	73 (76.8%)	81 (81.0%)
Censored	22 (23.2%)	19 (19.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.8, 0.9)
50%	1.5 (1.1, 1.7)	1.4 (1.4, 2.1)
75%	2.9 (2.1, NE)	3.3 (2.3, 5.6)
Survival probability (95% CI) at		
Month 6	18.6% (11.2%, 27.5%)	16.1% (9.4%, 24.4%)
Month 12	17.0% (9.9%, 25.9%)	14.5% (8.0%, 22.8%)
Month 18	17.0% (9.9%, 25.9%)	14.5% (8.0%, 22.8%)
Month 24	17.0% (9.9%, 25.9%)	14.5% (8.0%, 22.8%)
Month 30	17.0% (9.9%, 25.9%)	14.5% (8.0%, 22.8%)
Month 36	17.0% (9.9%, 25.9%)	14.5% (8.0%, 22.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.01 (0.731, 1.403)	
p-value of 2-sided stratified log-rank test	0.9096	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	73	81
0	20 (27.4%)	25 (30.9%)
1	3 (4.1%)	6 (7.4%)
2	7 (9.6%)	6 (7.4%)
3	2 (2.7%)	2 (2.5%)
>=4	41 (56.2%)	42 (51.9%)
p-value from Interaction Test[c]	0.9505	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	90 (92.8%)	73 (86.9%)
Censored	7 (7.2%)	11 (13.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	0.8 (0.7, 1.4)
50%	2.1 (1.4, 2.3)	1.5 (1.4, 2.8)
75%	4.2 (2.8, 9.1)	4.1 (3.5, 13.3)
Survival probability (95% CI) at		
Month 6	20.8% (13.4%, 29.4%)	22.3% (14.0%, 31.8%)
Month 12	14.6% (8.4%, 22.4%)	16.3% (9.1%, 25.5%)
Month 18	12.5% (6.8%, 19.9%)	11.7% (5.6%, 20.3%)
Month 24	11.4% (6.0%, 18.6%)	8.0% (3.0%, 16.3%)
Month 30	5.7% (2.2%, 11.7%)	6.0% (1.8%, 14.0%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.05 (0.761, 1.447)	
p-value of 2-sided stratified log-rank test	0.7653	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	90	73
0	30 (33.3%)	34 (46.6%)
1	4 (4.4%)	2 (2.7%)
2	10 (11.1%)	5 (6.8%)
3	4 (4.4%)	4 (5.5%)
>=4	42 (46.7%)	28 (38.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	87 (91.6%)	96 (96.0%)
Censored	8 (8.4%)	4 (4.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.8, 0.9)
50%	1.5 (1.1, 1.7)	1.4 (1.4, 2.1)
75%	2.9 (2.1, 6.2)	3.5 (2.3, 6.0)
Survival probability (95% CI) at		
Month 6	17.4% (10.5%, 25.8%)	17.3% (10.6%, 25.4%)
Month 12	14.0% (7.8%, 21.9%)	11.2% (6.0%, 18.4%)
Month 18	11.4% (5.9%, 19.0%)	7.1% (3.1%, 13.4%)
Month 24	8.9% (4.1%, 16.1%)	4.1% (1.3%, 9.4%)
Month 30	6.4% (2.4%, 13.0%)	4.1% (1.3%, 9.4%)
Month 36	6.4% (2.4%, 13.0%)	4.1% (1.3%, 9.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.99 (0.725, 1.345)	
p-value of 2-sided stratified log-rank test	0.9639	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	87	96
0	34 (39.1%)	40 (41.7%)
1	3 (3.4%)	6 (6.3%)
2	7 (8.0%)	6 (6.3%)
3	2 (2.3%)	2 (2.1%)
>=4	41 (47.1%)	42 (43.8%)
p-value from Interaction Test[c]	0.8200	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	15 (15.5%)	9 (10.7%)
Censored	82 (84.5%)	75 (89.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (16.7, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	86.1% (77.3%, 91.7%)	89.6% (80.3%, 94.7%)
Month 12	86.1% (77.3%, 91.7%)	88.0% (78.2%, 93.6%)
Month 18	82.8% (72.9%, 89.4%)	88.0% (78.2%, 93.6%)
Month 24	82.8% (72.9%, 89.4%)	88.0% (78.2%, 93.6%)
Month 30	82.8% (72.9%, 89.4%)	88.0% (78.2%, 93.6%)
Month 36	82.8% (72.9%, 89.4%)	88.0% (78.2%, 93.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.72 (0.317, 1.656)	
p-value of 2-sided stratified log-rank test	0.4445	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	15	9
0	6 (40.0%)	2 (22.2%)
1	2 (13.3%)	2 (22.2%)
2	3 (20.0%)	4 (44.4%)
3	1 (6.7%)	0
>=4	3 (20.0%)	1 (11.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	18 (18.9%)	17 (17.0%)
Censored	77 (81.1%)	83 (83.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	27.7 (11.0, NE)	37.3 (5.6, NE)
50%	NE (NE, NE)	NE (37.3, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	87.1% (77.9%, 92.7%)	84.1% (75.0%, 90.1%)
Month 12	82.6% (72.2%, 89.4%)	82.7% (73.3%, 89.1%)
Month 18	82.6% (72.2%, 89.4%)	82.7% (73.3%, 89.1%)
Month 24	78.0% (65.8%, 86.3%)	82.7% (73.3%, 89.1%)
Month 30	72.9% (59.2%, 82.6%)	82.7% (73.3%, 89.1%)
Month 36	72.9% (59.2%, 82.6%)	82.7% (73.3%, 89.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.91 (0.470, 1.782)	
p-value of 2-sided stratified log-rank test	0.7895	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	18	17
0	13 (72.2%)	12 (70.6%)
1	3 (16.7%)	2 (11.8%)
2	0	0
3	1 (5.6%)	0
>=4	1 (5.6%)	3 (17.6%)
p-value from Interaction Test[c]	0.6676	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	78 (80.4%)	62 (73.8%)
Censored	19 (19.6%)	22 (26.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	0.8 (0.7, 0.9)
50%	2.2 (1.6, 3.0)	1.4 (1.1, 2.3)
75%	9.3 (4.3, 12.9)	8.3 (2.8, NE)
Survival probability (95% CI) at		
Month 6	29.0% (20.0%, 38.5%)	26.9% (17.5%, 37.2%)
Month 12	17.5% (10.1%, 26.6%)	21.1% (12.3%, 31.5%)
Month 18	12.7% (6.3%, 21.4%)	19.0% (10.5%, 29.4%)
Month 24	12.7% (6.3%, 21.4%)	15.8% (7.6%, 26.8%)
Month 30	10.6% (4.7%, 19.3%)	15.8% (7.6%, 26.8%)
Month 36	10.6% (4.7%, 19.3%)	15.8% (7.6%, 26.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.89 (0.629, 1.254)	
p-value of 2-sided stratified log-rank test	0.5595	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	78	62
0	34 (43.6%)	25 (40.3%)
1	14 (17.9%)	6 (9.7%)
2	6 (7.7%)	7 (11.3%)
3	7 (9.0%)	7 (11.3%)
>=4	17 (21.8%)	17 (27.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	68 (71.6%)	75 (75.0%)
Censored	27 (28.4%)	25 (25.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.4 (0.8, 1.6)
50%	2.3 (1.5, 3.7)	2.8 (1.8, 3.7)
75%	13.2 (5.8, 23.1)	16.4 (4.6, 40.2)
Survival probability (95% CI) at		
Month 6	34.9% (24.8%, 45.1%)	31.4% (22.3%, 40.9%)
Month 12	26.8% (17.4%, 37.2%)	26.0% (17.3%, 35.5%)
Month 18	19.6% (11.1%, 29.8%)	19.8% (11.5%, 29.8%)
Month 24	12.4% (5.3%, 22.8%)	15.1% (7.4%, 25.3%)
Month 30	12.4% (5.3%, 22.8%)	15.1% (7.4%, 25.3%)
Month 36	12.4% (5.3%, 22.8%)	15.1% (7.4%, 25.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.10 (0.781, 1.538)	
p-value of 2-sided stratified log-rank test	0.6089	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	68	75
0	37 (54.4%)	39 (52.0%)
1	12 (17.6%)	16 (21.3%)
2	6 (8.8%)	8 (10.7%)
3	5 (7.4%)	2 (2.7%)
>=4	8 (11.8%)	10 (13.3%)
p-value from Interaction Test[c]	0.4939	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	89 (91.8%)	71 (84.5%)
Censored	8 (8.2%)	13 (15.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	0.8 (0.7, 0.9)
50%	2.2 (1.6, 3.0)	1.4 (1.1, 2.3)
75%	6.1 (4.6, 11.1)	5.4 (2.8, 16.1)
Survival probability (95% CI) at		
Month 6	26.4% (18.0%, 35.6%)	24.0% (15.3%, 33.8%)
Month 12	13.2% (7.3%, 20.9%)	17.8% (10.1%, 27.3%)
Month 18	9.9% (4.9%, 17.0%)	14.6% (7.6%, 23.8%)
Month 24	8.7% (4.0%, 15.6%)	9.1% (3.6%, 17.7%)
Month 30	7.4% (3.2%, 14.1%)	7.3% (2.5%, 15.6%)
Month 36	5.6% (1.9%, 12.3%)	7.3% (2.5%, 15.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.90 (0.647, 1.241)	
p-value of 2-sided stratified log-rank test	0.5657	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	89	71
0	45 (50.6%)	34 (47.9%)
1	14 (15.7%)	6 (8.5%)
2	6 (6.7%)	7 (9.9%)
3	7 (7.9%)	7 (9.9%)
>=4	17 (19.1%)	17 (23.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	84 (88.4%)	93 (93.0%)
Censored	11 (11.6%)	7 (7.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.4 (0.8, 1.6)
50%	2.2 (1.5, 3.4)	2.8 (2.1, 3.9)
75%	11.8 (5.6, 17.0)	10.8 (5.6, 16.4)
Survival probability (95% CI) at		
Month 6	33.2% (23.7%, 42.9%)	32.7% (23.6%, 42.0%)
Month 12	24.6% (16.1%, 34.0%)	23.2% (15.4%, 32.0%)
Month 18	15.6% (8.8%, 24.2%)	12.6% (6.9%, 20.1%)
Month 24	7.8% (3.2%, 15.0%)	7.4% (3.3%, 13.7%)
Month 30	4.7% (1.4%, 11.3%)	5.3% (2.0%, 11.0%)
Month 36	4.7% (1.4%, 11.3%)	5.3% (2.0%, 11.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.13 (0.829, 1.533)	
p-value of 2-sided stratified log-rank test	0.4472	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	84	93
0	53 (63.1%)	57 (61.3%)
1	12 (14.3%)	16 (17.2%)
2	6 (7.1%)	8 (8.6%)
3	5 (6.0%)	2 (2.2%)
>=4	8 (9.5%)	10 (10.8%)
p-value from Interaction Test[c]	0.3917	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	24 (24.7%)	18 (21.4%)
Censored	73 (75.3%)	66 (78.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	21.4 (2.9, NE)	21.5 (3.5, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	79.7% (70.1%, 86.6%)	83.5% (73.2%, 90.1%)
Month 12	76.9% (66.7%, 84.3%)	80.0% (68.9%, 87.5%)
Month 18	75.1% (64.5%, 83.0%)	75.9% (63.7%, 84.5%)
Month 24	73.3% (62.1%, 81.6%)	73.3% (60.2%, 82.7%)
Month 30	73.3% (62.1%, 81.6%)	73.3% (60.2%, 82.7%)
Month 36	73.3% (62.1%, 81.6%)	73.3% (60.2%, 82.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.93 (0.502, 1.715)	
p-value of 2-sided stratified log-rank test	0.8086	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	24	18
0	15 (62.5%)	8 (44.4%)
1	1 (4.2%)	5 (27.8%)
2	3 (12.5%)	1 (5.6%)
3	1 (4.2%)	0
>=4	4 (16.7%)	4 (22.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	33 (34.7%)	22 (22.0%)
Censored	62 (65.3%)	78 (78.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.8, 4.4)	NE (2.8, NE)
50%	NE (16.9, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	64.2% (53.1%, 73.4%)	78.7% (68.9%, 85.7%)
Month 12	62.7% (51.4%, 72.0%)	75.5% (65.0%, 83.3%)
Month 18	60.7% (49.1%, 70.4%)	75.5% (65.0%, 83.3%)
Month 24	60.7% (49.1%, 70.4%)	75.5% (65.0%, 83.3%)
Month 30	60.7% (49.1%, 70.4%)	75.5% (65.0%, 83.3%)
Month 36	60.7% (49.1%, 70.4%)	75.5% (65.0%, 83.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.53 (0.306, 0.906)	
p-value of 2-sided stratified log-rank test	0.0194	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	33	22
0	17 (51.5%)	12 (54.5%)
1	6 (18.2%)	1 (4.5%)
2	2 (6.1%)	5 (22.7%)
3	2 (6.1%)	0
>=4	6 (18.2%)	4 (18.2%)
p-value from Interaction Test[c]	0.1576	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	89 (91.8%)	78 (92.9%)
Censored	8 (8.2%)	6 (7.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (NE, NE)	0.7 (NE, NE)
50%	0.8 (0.7, 0.8)	0.8 (0.7, 0.8)
75%	0.9 (0.9, 1.0)	0.9 (0.8, 1.0)
Survival probability (95% CI) at		
Month 6	6.3% (2.6%, 12.4%)	3.7% (1.0%, 9.5%)
Month 12	6.3% (2.6%, 12.4%)	3.7% (1.0%, 9.5%)
Month 18	6.3% (2.6%, 12.4%)	3.7% (1.0%, 9.5%)
Month 24	6.3% (2.6%, 12.4%)	3.7% (1.0%, 9.5%)
Month 30	6.3% (2.6%, 12.4%)	NE (NE, NE)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.78 (0.573, 1.074)	
p-value of 2-sided stratified log-rank test	0.1337	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	89	78
0	13 (14.6%)	12 (15.4%)
1	14 (15.7%)	10 (12.8%)
2	6 (6.7%)	8 (10.3%)
3	8 (9.0%)	7 (9.0%)
>=4	48 (53.9%)	41 (52.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	88 (92.6%)	92 (92.0%)
Censored	7 (7.4%)	8 (8.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (NE, NE)	0.7 (NE, NE)
50%	0.8 (0.7, 0.8)	0.8 (NE, NE)
75%	0.9 (0.8, 0.9)	0.9 (0.8, 1.0)
Survival probability (95% CI) at		
Month 6	1.1% (0.1%, 5.5%)	6.2% (2.5%, 12.2%)
Month 12	1.1% (0.1%, 5.5%)	6.2% (2.5%, 12.2%)
Month 18	1.1% (0.1%, 5.5%)	3.1% (0.4%, 11.1%)
Month 24	1.1% (0.1%, 5.5%)	3.1% (0.4%, 11.1%)
Month 30	1.1% (0.1%, 5.5%)	3.1% (0.4%, 11.1%)
Month 36	1.1% (0.1%, 5.5%)	3.1% (0.4%, 11.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.25 (0.916, 1.706)	
p-value of 2-sided stratified log-rank test	0.1206	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	88	92
0	7 (8.0%)	13 (14.1%)
1	14 (15.9%)	15 (16.3%)
2	12 (13.6%)	9 (9.8%)
3	5 (5.7%)	4 (4.3%)
>=4	50 (56.8%)	51 (55.4%)
p-value from Interaction Test[c]	0.0781	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	94 (96.9%)	80 (95.2%)
Censored	3 (3.1%)	4 (4.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (NE, NE)	0.7 (NE, NE)
50%	0.8 (0.7, 0.9)	0.8 (0.7, 0.8)
75%	0.9 (0.9, 1.0)	0.9 (0.8, 1.0)
Survival probability (95% CI) at		
Month 6	6.3% (2.6%, 12.3%)	3.7% (1.0%, 9.4%)
Month 12	5.2% (1.9%, 10.9%)	3.7% (1.0%, 9.4%)
Month 18	4.2% (1.4%, 9.5%)	3.7% (1.0%, 9.4%)
Month 24	4.2% (1.4%, 9.5%)	3.7% (1.0%, 9.4%)
Month 30	2.1% (0.4%, 6.6%)	0 (NE, NE)
Month 36	NE (NE, NE)	0 (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.78 (0.575, 1.070)	
p-value of 2-sided stratified log-rank test	0.1346	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	94	80
0	18 (19.1%)	14 (17.5%)
1	14 (14.9%)	10 (12.5%)
2	6 (6.4%)	8 (10.0%)
3	8 (8.5%)	7 (8.8%)
>=4	48 (51.1%)	41 (51.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	91 (95.8%)	97 (97.0%)
Censored	4 (4.2%)	3 (3.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (NE, NE)	0.7 (NE, NE)
50%	0.8 (0.7, 0.8)	0.8 (NE, NE)
75%	0.9 (0.8, 0.9)	0.9 (0.8, 1.1)
Survival probability (95% CI) at		
Month 6	1.1% (0.1%, 5.3%)	7.1% (3.1%, 13.4%)
Month 12	1.1% (0.1%, 5.3%)	5.1% (1.9%, 10.7%)
Month 18	1.1% (0.1%, 5.3%)	2.0% (0.4%, 6.5%)
Month 24	1.1% (0.1%, 5.3%)	1.0% (0.1%, 5.0%)
Month 30	1.1% (0.1%, 5.3%)	1.0% (0.1%, 5.0%)
Month 36	1.1% (0.1%, 5.3%)	1.0% (0.1%, 5.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.22 (0.895, 1.655)	
p-value of 2-sided stratified log-rank test	0.1524	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	91	97
0	10 (11.0%)	18 (18.6%)
1	14 (15.4%)	15 (15.5%)
2	12 (13.2%)	9 (9.3%)
3	5 (5.5%)	4 (4.1%)
>=4	50 (54.9%)	51 (52.6%)
p-value from Interaction Test[c]	0.1177	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	8 (8.2%)	3 (3.6%)
Censored	89 (91.8%)	81 (96.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (NE, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	96.6% (89.9%, 98.9%)	98.5% (90.0%, 99.8%)
Month 12	89.7% (80.3%, 94.7%)	96.7% (87.4%, 99.2%)
Month 18	89.7% (80.3%, 94.7%)	94.8% (84.6%, 98.3%)
Month 24	89.7% (80.3%, 94.7%)	94.8% (84.6%, 98.3%)
Month 30	89.7% (80.3%, 94.7%)	94.8% (84.6%, 98.3%)
Month 36	89.7% (80.3%, 94.7%)	94.8% (84.6%, 98.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.39 (0.102, 1.463)	
p-value of 2-sided stratified log-rank test	0.1466	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	8	3
0	4 (50.0%)	2 (66.7%)
1	0	0
2	0	0
3	0	0
>=4	4 (50.0%)	1 (33.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	7 (7.4%)	6 (6.0%)
Censored	88 (92.6%)	94 (94.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (NE, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	96.4% (89.1%, 98.8%)	98.9% (92.7%, 99.8%)
Month 12	90.4% (80.7%, 95.3%)	92.8% (83.4%, 97.0%)
Month 18	90.4% (80.7%, 95.3%)	91.1% (81.0%, 95.9%)
Month 24	90.4% (80.7%, 95.3%)	91.1% (81.0%, 95.9%)
Month 30	90.4% (80.7%, 95.3%)	91.1% (81.0%, 95.9%)
Month 36	90.4% (80.7%, 95.3%)	91.1% (81.0%, 95.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.76 (0.254, 2.291)	
p-value of 2-sided stratified log-rank test	0.6287	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	7	6
0	3 (42.9%)	4 (66.7%)
1	0	0
2	0	0
3	0	0
>=4	4 (57.1%)	2 (33.3%)
p-value from Interaction Test[c]	0.5060	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	70 (72.2%)	60 (71.4%)
Censored	27 (27.8%)	24 (28.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.8)	0.8 (0.7, 0.9)
50%	1.4 (0.9, 1.6)	1.4 (1.2, 2.1)
75%	24.2 (3.0, NE)	3.8 (2.9, NE)
Survival probability (95% CI) at		
Month 6	28.0% (19.3%, 37.3%)	24.9% (16.0%, 34.8%)
Month 12	26.4% (17.9%, 35.8%)	24.9% (16.0%, 34.8%)
Month 18	26.4% (17.9%, 35.8%)	24.9% (16.0%, 34.8%)
Month 24	26.4% (17.9%, 35.8%)	24.9% (16.0%, 34.8%)
Month 30	24.2% (15.6%, 33.9%)	24.9% (16.0%, 34.8%)
Month 36	24.2% (15.6%, 33.9%)	24.9% (16.0%, 34.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.03 (0.724, 1.460)	
p-value of 2-sided stratified log-rank test	0.8674	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	70	60
0	23 (32.9%)	22 (36.7%)
1	8 (11.4%)	10 (16.7%)
2	9 (12.9%)	7 (11.7%)
3	6 (8.6%)	5 (8.3%)
>=4	24 (34.3%)	16 (26.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	68 (71.6%)	69 (69.0%)
Censored	27 (28.4%)	31 (31.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 1.1)
50%	1.4 (0.9, 2.1)	1.7 (1.4, 3.5)
75%	17.1 (2.1, NE)	31.3 (7.4, NE)
Survival probability (95% CI) at		
Month 6	27.2% (18.3%, 36.8%)	35.0% (25.6%, 44.6%)
Month 12	27.2% (18.3%, 36.8%)	32.3% (23.0%, 41.9%)
Month 18	23.5% (14.9%, 33.4%)	25.8% (16.8%, 35.7%)
Month 24	23.5% (14.9%, 33.4%)	25.8% (16.8%, 35.7%)
Month 30	23.5% (14.9%, 33.4%)	25.8% (16.8%, 35.7%)
Month 36	21.4% (12.8%, 31.4%)	22.5% (13.2%, 33.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.22 (0.866, 1.722)	
p-value of 2-sided stratified log-rank test	0.2421	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	68	69
0	26 (38.2%)	22 (31.9%)
1	5 (7.4%)	15 (21.7%)
2	6 (8.8%)	7 (10.1%)
3	8 (11.8%)	2 (2.9%)
>=4	23 (33.8%)	23 (33.3%)
p-value from Interaction Test[c]	0.4548	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	82 (84.5%)	70 (83.3%)
Censored	15 (15.5%)	14 (16.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.8)	0.8 (0.7, 0.9)
50%	1.4 (0.9, 1.6)	1.4 (1.0, 2.1)
75%	6.8 (3.0, 24.6)	4.0 (2.9, 18.2)
Survival probability (95% CI) at		
Month 6	26.6% (18.2%, 35.8%)	24.4% (15.7%, 34.1%)
Month 12	21.0% (13.4%, 29.8%)	24.4% (15.7%, 34.1%)
Month 18	18.4% (11.2%, 27.0%)	17.2% (9.8%, 26.4%)
Month 24	18.4% (11.2%, 27.0%)	13.9% (7.2%, 22.9%)
Month 30	12.7% (6.6%, 20.9%)	11.9% (5.6%, 20.8%)
Month 36	12.7% (6.6%, 20.9%)	11.9% (5.6%, 20.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.03 (0.740, 1.422)	
p-value of 2-sided stratified log-rank test	0.8694	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	82	70
0	35 (42.7%)	32 (45.7%)
1	8 (9.8%)	10 (14.3%)
2	9 (11.0%)	7 (10.0%)
3	6 (7.3%)	5 (7.1%)
>=4	24 (29.3%)	16 (22.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	81 (85.3%)	86 (86.0%)
Censored	14 (14.7%)	14 (14.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 1.1)
50%	1.4 (1.0, 2.1)	1.9 (1.4, 3.5)
75%	9.7 (2.2, 20.1)	14.7 (7.4, 21.5)
Survival probability (95% CI) at		
Month 6	26.1% (17.6%, 35.3%)	35.7% (26.4%, 45.1%)
Month 12	25.0% (16.7%, 34.1%)	28.4% (19.8%, 37.5%)
Month 18	19.0% (11.7%, 27.7%)	17.5% (10.7%, 25.8%)
Month 24	15.4% (8.8%, 23.7%)	15.1% (8.7%, 23.1%)
Month 30	15.4% (8.8%, 23.7%)	15.1% (8.7%, 23.1%)
Month 36	13.0% (6.9%, 20.9%)	10.6% (5.1%, 18.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.13 (0.827, 1.546)	
p-value of 2-sided stratified log-rank test	0.4256	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	81	86
0	39 (48.1%)	39 (45.3%)
1	5 (6.2%)	15 (17.4%)
2	6 (7.4%)	7 (8.1%)
3	8 (9.9%)	2 (2.3%)
>=4	23 (28.4%)	23 (26.7%)
p-value from Interaction Test[c]	0.6288	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	11 (11.3%)	8 (9.5%)
Censored	86 (88.7%)	76 (90.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (28.7, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	91.3% (83.4%, 95.6%)	89.3% (79.7%, 94.5%)
Month 12	89.9% (81.3%, 94.6%)	89.3% (79.7%, 94.5%)
Month 18	89.9% (81.3%, 94.6%)	89.3% (79.7%, 94.5%)
Month 24	88.1% (78.6%, 93.5%)	89.3% (79.7%, 94.5%)
Month 30	85.6% (74.7%, 92.1%)	89.3% (79.7%, 94.5%)
Month 36	85.6% (74.7%, 92.1%)	89.3% (79.7%, 94.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.92 (0.368, 2.281)	
p-value of 2-sided stratified log-rank test	0.8500	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	11	8
0	5 (45.5%)	3 (37.5%)
1	2 (18.2%)	1 (12.5%)
2	1 (9.1%)	2 (25.0%)
3	0	0
>=4	3 (27.3%)	2 (25.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	12 (12.6%)	12 (12.0%)
Censored	83 (87.4%)	88 (88.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (19.5, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	89.5% (80.7%, 94.4%)	89.4% (81.3%, 94.2%)
Month 12	86.4% (76.6%, 92.3%)	86.6% (77.5%, 92.2%)
Month 18	86.4% (76.6%, 92.3%)	86.6% (77.5%, 92.2%)
Month 24	84.0% (72.9%, 90.8%)	86.6% (77.5%, 92.2%)
Month 30	84.0% (72.9%, 90.8%)	86.6% (77.5%, 92.2%)
Month 36	84.0% (72.9%, 90.8%)	86.6% (77.5%, 92.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.98 (0.440, 2.201)	
p-value of 2-sided stratified log-rank test	0.9687	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	12	12
0	8 (66.7%)	4 (33.3%)
1	3 (25.0%)	2 (16.7%)
2	0	4 (33.3%)
3	0	1 (8.3%)
>=4	1 (8.3%)	1 (8.3%)
p-value from Interaction Test[c]	0.9573	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	61 (67.8%)	67 (77.0%)
Censored	29 (32.2%)	20 (23.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 1.5)	1.0 (0.8, 1.4)
50%	2.8 (2.1, 4.1)	3.4 (1.5, 4.1)
75%	27.9 (7.6, NE)	10.9 (4.4, 24.5)
Survival probability (95% CI) at		
Month 6	35.4% (25.3%, 45.6%)	30.6% (20.9%, 40.9%)
Month 12	30.3% (20.5%, 40.7%)	24.2% (15.2%, 34.4%)
Month 18	27.8% (17.9%, 38.6%)	22.5% (13.7%, 32.7%)
Month 24	25.0% (15.1%, 36.3%)	15.0% (7.1%, 25.7%)
Month 30	21.4% (11.4%, 33.5%)	12.0% (4.8%, 22.9%)
Month 36	21.4% (11.4%, 33.5%)	9.0% (2.8%, 19.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.85 (0.603, 1.211)	
p-value of 2-sided stratified log-rank test	0.3708	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	61	67
0	31 (50.8%)	37 (55.2%)
1	14 (23.0%)	7 (10.4%)
2	3 (4.9%)	7 (10.4%)
3	4 (6.6%)	4 (6.0%)
>=4	9 (14.8%)	12 (17.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	26 (74.3%)	22 (66.7%)
Censored	9 (25.7%)	11 (33.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 2.6)	1.5 (0.8, 2.3)
50%	3.5 (1.7, 5.4)	3.2 (2.1, 15.4)
75%	11.6 (4.1, NE)	16.8 (3.5, NE)
Survival probability (95% CI) at		
Month 6	32.5% (17.7%, 48.2%)	36.7% (19.5%, 54.0%)
Month 12	19.2% (6.7%, 36.6%)	36.7% (19.5%, 54.0%)
Month 18	19.2% (6.7%, 36.6%)	24.4% (10.3%, 41.8%)
Month 24	19.2% (6.7%, 36.6%)	24.4% (10.3%, 41.8%)
Month 30	19.2% (6.7%, 36.6%)	24.4% (10.3%, 41.8%)
Month 36	19.2% (6.7%, 36.6%)	19.6% (6.9%, 36.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.19 (0.659, 2.157)	
p-value of 2-sided stratified log-rank test	0.5492	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	26	22
0	14 (53.8%)	9 (40.9%)
1	2 (7.7%)	3 (13.6%)
2	1 (3.8%)	0
3	2 (7.7%)	2 (9.1%)
>=4	7 (26.9%)	8 (36.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	48 (71.6%)	41 (64.1%)
Censored	19 (28.4%)	23 (35.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.1)	2.1 (1.0, 2.8)
50%	2.9 (2.1, 4.6)	8.0 (2.8, 15.5)
75%	9.1 (4.6, 39.6)	34.1 (15.5, NE)
Survival probability (95% CI) at		
Month 6	30.0% (18.6%, 42.3%)	54.3% (41.1%, 65.8%)
Month 12	20.0% (10.1%, 32.3%)	43.5% (30.7%, 55.6%)
Month 18	17.2% (7.9%, 29.4%)	36.5% (23.9%, 49.2%)
Month 24	17.2% (7.9%, 29.4%)	26.5% (14.3%, 40.4%)
Month 30	13.7% (5.3%, 26.1%)	26.5% (14.3%, 40.4%)
Month 36	13.7% (5.3%, 26.1%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.59 (1.033, 2.432)	
p-value of 2-sided stratified log-rank test	0.0328	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	48	41
0	24 (50.0%)	27 (65.9%)
1	4 (8.3%)	7 (17.1%)
2	8 (16.7%)	2 (4.9%)
3	2 (4.2%)	1 (2.4%)
>=4	10 (20.8%)	4 (9.8%)
p-value from Interaction Test[c]	0.0941	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	72 (80.0%)	82 (94.3%)
Censored	18 (20.0%)	5 (5.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 1.6)	1.0 (0.8, 1.4)
50%	2.8 (2.1, 3.7)	3.4 (2.1, 4.1)
75%	16.5 (5.9, 26.5)	10.0 (4.5, 17.3)
Survival probability (95% CI) at		
Month 6	34.0% (24.2%, 43.9%)	29.5% (20.3%, 39.4%)
Month 12	25.8% (16.9%, 35.6%)	22.5% (14.3%, 31.8%)
Month 18	24.0% (15.3%, 33.9%)	14.2% (7.8%, 22.5%)
Month 24	18.5% (10.4%, 28.4%)	5.9% (2.2%, 12.3%)
Month 30	11.1% (4.8%, 20.3%)	4.7% (1.5%, 10.7%)
Month 36	11.1% (4.8%, 20.3%)	3.5% (0.9%, 9.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.82 (0.597, 1.128)	
p-value of 2-sided stratified log-rank test	0.2237	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	72	82
0	42 (58.3%)	52 (63.4%)
1	14 (19.4%)	7 (8.5%)
2	3 (4.2%)	7 (8.5%)
3	4 (5.6%)	4 (4.9%)
>=4	9 (12.5%)	12 (14.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	30 (85.7%)	26 (78.8%)
Censored	5 (14.3%)	7 (21.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 2.6)	1.5 (0.8, 2.3)
50%	3.5 (1.7, 5.4)	3.2 (2.1, 4.6)
75%	8.4 (4.1, 16.5)	15.4 (3.5, 39.1)
Survival probability (95% CI) at		
Month 6	32.5% (17.7%, 48.2%)	31.1% (15.6%, 48.0%)
Month 12	20.3% (8.7%, 35.2%)	31.1% (15.6%, 48.0%)
Month 18	10.1% (2.7%, 23.5%)	20.7% (8.4%, 36.8%)
Month 24	10.1% (2.7%, 23.5%)	20.7% (8.4%, 36.8%)
Month 30	10.1% (2.7%, 23.5%)	20.7% (8.4%, 36.8%)
Month 36	10.1% (2.7%, 23.5%)	17.3% (6.3%, 32.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.22 (0.704, 2.099)	
p-value of 2-sided stratified log-rank test	0.4754	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	30	26
0	18 (60.0%)	13 (50.0%)
1	2 (6.7%)	3 (11.5%)
2	1 (3.3%)	0
3	2 (6.7%)	2 (7.7%)
>=4	7 (23.3%)	8 (30.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	58 (86.6%)	57 (89.1%)
Censored	9 (13.4%)	7 (10.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.1)	2.1 (0.8, 2.8)
50%	2.9 (2.1, 3.7)	7.5 (2.8, 11.8)
75%	7.0 (4.6, 9.7)	19.8 (12.0, 27.2)
Survival probability (95% CI) at		
Month 6	29.3% (18.7%, 40.8%)	53.1% (40.2%, 64.4%)
Month 12	13.9% (6.6%, 23.9%)	37.5% (25.8%, 49.1%)
Month 18	11.9% (5.2%, 21.6%)	26.6% (16.5%, 37.7%)
Month 24	11.9% (5.2%, 21.6%)	15.9% (8.1%, 26.2%)
Month 30	8.0% (2.7%, 16.9%)	11.6% (4.9%, 21.6%)
Month 36	8.0% (2.7%, 16.9%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.47 (1.010, 2.143)	
p-value of 2-sided stratified log-rank test	0.0426	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	58	57
0	34 (58.6%)	43 (75.4%)
1	4 (6.9%)	7 (12.3%)
2	8 (13.8%)	2 (3.5%)
3	2 (3.4%)	1 (1.8%)
>=4	10 (17.2%)	4 (7.0%)
p-value from Interaction Test[c]	0.0803	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	31 (34.4%)	25 (28.7%)
Censored	59 (65.6%)	62 (71.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (1.0, 20.2)	3.6 (1.4, NE)
50%	NE (23.8, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	67.7% (56.7%, 76.4%)	73.5% (62.6%, 81.7%)
Month 12	67.7% (56.7%, 76.4%)	70.3% (58.8%, 79.1%)
Month 18	67.7% (56.7%, 76.4%)	68.1% (56.1%, 77.4%)
Month 24	61.3% (49.0%, 71.5%)	68.1% (56.1%, 77.4%)
Month 30	61.3% (49.0%, 71.5%)	68.1% (56.1%, 77.4%)
Month 36	61.3% (49.0%, 71.5%)	68.1% (56.1%, 77.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.81 (0.481, 1.381)	
p-value of 2-sided stratified log-rank test	0.4472	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	31	25
0	12 (38.7%)	13 (52.0%)
1	9 (29.0%)	1 (4.0%)
2	1 (3.2%)	3 (12.0%)
3	1 (3.2%)	3 (12.0%)
>=4	8 (25.8%)	5 (20.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	9 (25.7%)	6 (18.2%)
Censored	26 (74.3%)	27 (81.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	16.9 (0.8, NE)	NE (0.8, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	79.6% (61.9%, 89.7%)	79.0% (59.0%, 90.0%)
Month 12	79.6% (61.9%, 89.7%)	79.0% (59.0%, 90.0%)
Month 18	71.2% (51.3%, 84.1%)	79.0% (59.0%, 90.0%)
Month 24	71.2% (51.3%, 84.1%)	79.0% (59.0%, 90.0%)
Month 30	71.2% (51.3%, 84.1%)	79.0% (59.0%, 90.0%)
Month 36	71.2% (51.3%, 84.1%)	79.0% (59.0%, 90.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.84 (0.298, 2.355)	
p-value of 2-sided stratified log-rank test	0.7365	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	9	6
0	3 (33.3%)	4 (66.7%)
1	4 (44.4%)	1 (16.7%)
2	1 (11.1%)	0
3	0	0
>=4	1 (11.1%)	1 (16.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	14 (20.9%)	9 (14.1%)
Censored	53 (79.1%)	55 (85.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (0.9, NE)	NE (2.2, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	77.0% (64.2%, 85.7%)	85.3% (73.6%, 92.1%)
Month 12	77.0% (64.2%, 85.7%)	85.3% (73.6%, 92.1%)
Month 18	77.0% (64.2%, 85.7%)	85.3% (73.6%, 92.1%)
Month 24	77.0% (64.2%, 85.7%)	85.3% (73.6%, 92.1%)
Month 30	77.0% (64.2%, 85.7%)	85.3% (73.6%, 92.1%)
Month 36	77.0% (64.2%, 85.7%)	85.3% (73.6%, 92.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.58 (0.253, 1.350)	
p-value of 2-sided stratified log-rank test	0.2073	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	14	9
0	4 (28.6%)	1 (11.1%)
1	4 (28.6%)	3 (33.3%)
2	1 (7.1%)	0
3	0	0
>=4	5 (35.7%)	5 (55.6%)
p-value from Interaction Test[c]	0.8177	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	48 (53.3%)	54 (62.1%)
Censored	42 (46.7%)	33 (37.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (1.4, 2.1)	1.4 (0.9, 2.1)
50%	5.2 (2.8, NE)	5.6 (2.3, 15.4)
75%	NE (35.4, NE)	32.3 (21.7, NE)
Survival probability (95% CI) at		
Month 6	49.3% (38.2%, 59.5%)	49.6% (38.4%, 59.8%)
Month 12	44.5% (33.3%, 55.0%)	41.6% (30.4%, 52.4%)
Month 18	42.7% (31.5%, 53.4%)	37.8% (26.7%, 48.9%)
Month 24	42.7% (31.5%, 53.4%)	32.4% (21.0%, 44.3%)
Month 30	42.7% (31.5%, 53.4%)	26.5% (15.3%, 39.1%)
Month 36	38.0% (25.0%, 50.8%)	23.2% (12.2%, 36.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.82 (0.554, 1.208)	
p-value of 2-sided stratified log-rank test	0.3017	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	48	54
0	31 (64.6%)	27 (50.0%)
1	8 (16.7%)	7 (13.0%)
2	2 (4.2%)	6 (11.1%)
3	2 (4.2%)	3 (5.6%)
>=4	5 (10.4%)	11 (20.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	21 (60.0%)	13 (39.4%)
Censored	14 (40.0%)	20 (60.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.3 (0.7, 2.1)	1.6 (0.7, 18.2)
50%	3.9 (1.6, NE)	37.4 (2.2, NE)
75%	NE (11.1, NE)	NE (37.4, NE)
Survival probability (95% CI) at		
Month 6	47.4% (30.1%, 62.8%)	61.0% (40.5%, 76.4%)
Month 12	40.6% (23.9%, 56.6%)	61.0% (40.5%, 76.4%)
Month 18	36.1% (19.7%, 52.7%)	61.0% (40.5%, 76.4%)
Month 24	36.1% (19.7%, 52.7%)	56.3% (35.6%, 72.7%)
Month 30	36.1% (19.7%, 52.7%)	56.3% (35.6%, 72.7%)
Month 36	36.1% (19.7%, 52.7%)	56.3% (35.6%, 72.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.81 (0.872, 3.768)	
p-value of 2-sided stratified log-rank test	0.1032	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	21	13
0	10 (47.6%)	11 (84.6%)
1	8 (38.1%)	0
2	3 (14.3%)	1 (7.7%)
3	0	1 (7.7%)
>=4	0	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	31 (46.3%)	28 (43.8%)
Censored	36 (53.7%)	36 (56.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.9, 2.8)	2.5 (1.4, 3.5)
50%	22.0 (2.8, NE)	20.7 (3.7, NE)
75%	NE (29.4, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	59.4% (45.7%, 70.8%)	61.9% (48.4%, 72.8%)
Month 12	52.7% (38.6%, 64.9%)	57.6% (43.9%, 69.2%)
Month 18	50.0% (35.9%, 62.7%)	51.9% (37.4%, 64.5%)
Month 24	46.5% (31.8%, 59.9%)	47.5% (32.1%, 61.5%)
Month 30	38.7% (23.6%, 53.6%)	47.5% (32.1%, 61.5%)
Month 36	38.7% (23.6%, 53.6%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.16 (0.695, 1.939)	
p-value of 2-sided stratified log-rank test	0.5681	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	31	28
0	21 (67.7%)	18 (64.3%)
1	4 (12.9%)	4 (14.3%)
2	2 (6.5%)	2 (7.1%)
3	1 (3.2%)	2 (7.1%)
>=4	3 (9.7%)	2 (7.1%)
p-value from Interaction Test[c]	0.1949	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	68 (75.6%)	77 (88.5%)
Censored	22 (24.4%)	10 (11.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (1.4, 2.1)	1.4 (0.9, 2.1)
50%	5.2 (2.8, 11.4)	5.5 (2.4, 9.8)
75%	29.7 (14.9, NE)	21.5 (13.2, 27.0)
Survival probability (95% CI) at		
Month 6	47.5% (36.8%, 57.6%)	47.6% (36.8%, 57.7%)
Month 12	37.3% (27.1%, 47.5%)	37.7% (27.4%, 47.9%)
Month 18	34.7% (24.7%, 44.9%)	27.6% (18.5%, 37.5%)
Month 24	28.0% (18.7%, 38.1%)	17.6% (10.2%, 26.6%)
Month 30	24.0% (15.3%, 33.8%)	12.6% (6.5%, 20.8%)
Month 36	18.5% (10.4%, 28.4%)	9.6% (4.3%, 17.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.79 (0.569, 1.098)	
p-value of 2-sided stratified log-rank test	0.1583	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	68	77
0	51 (75.0%)	50 (64.9%)
1	8 (11.8%)	7 (9.1%)
2	2 (2.9%)	6 (7.8%)
3	2 (2.9%)	3 (3.9%)
>=4	5 (7.4%)	11 (14.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	26 (74.3%)	21 (63.6%)
Censored	9 (25.7%)	12 (36.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.3 (0.7, 2.1)	1.6 (0.7, 5.6)
50%	3.9 (1.6, 16.5)	18.1 (2.2, 36.1)
75%	22.4 (11.1, NE)	37.4 (31.7, NE)
Survival probability (95% CI) at		
Month 6	47.4% (30.1%, 62.8%)	58.6% (38.8%, 74.0%)
Month 12	41.3% (24.8%, 57.0%)	58.6% (38.8%, 74.0%)
Month 18	31.0% (16.1%, 47.1%)	51.3% (31.9%, 67.7%)
Month 24	24.1% (11.0%, 39.9%)	44.0% (25.5%, 61.0%)
Month 30	20.6% (8.6%, 36.2%)	44.0% (25.5%, 61.0%)
Month 36	20.6% (8.6%, 36.2%)	35.8% (18.6%, 53.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.50 (0.823, 2.720)	
p-value of 2-sided stratified log-rank test	0.1809	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	26	21
0	15 (57.7%)	19 (90.5%)
1	8 (30.8%)	0
2	3 (11.5%)	1 (4.8%)
3	0	1 (4.8%)
>=4	0	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	49 (73.1%)	51 (79.7%)
Censored	18 (26.9%)	13 (20.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.9 (0.9, 2.6)	2.4 (1.4, 3.5)
50%	6.1 (2.8, 12.7)	10.2 (3.7, 13.2)
75%	28.5 (13.2, NE)	22.1 (13.4, NE)
Survival probability (95% CI) at		
Month 6	52.7% (39.8%, 64.1%)	59.4% (46.3%, 70.2%)
Month 12	39.3% (27.1%, 51.2%)	44.6% (32.1%, 56.4%)
Month 18	33.9% (22.3%, 45.8%)	33.0% (21.7%, 44.8%)
Month 24	27.9% (17.1%, 39.8%)	23.9% (13.9%, 35.3%)
Month 30	19.9% (10.6%, 31.4%)	17.8% (9.1%, 28.8%)
Month 36	19.9% (10.6%, 31.4%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.99 (0.666, 1.472)	
p-value of 2-sided stratified log-rank test	0.9578	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	49	51
0	39 (79.6%)	41 (80.4%)
1	4 (8.2%)	4 (7.8%)
2	2 (4.1%)	2 (3.9%)
3	1 (2.0%)	2 (3.9%)
>=4	3 (6.1%)	2 (3.9%)
p-value from Interaction Test[c]	0.2045	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	37 (41.1%)	33 (37.9%)
Censored	53 (58.9%)	54 (62.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.9 (1.5, 5.7)	2.1 (1.0, 8.3)
50%	NE (8.5, NE)	NE (10.3, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	65.5% (54.2%, 74.6%)	66.8% (55.7%, 75.8%)
Month 12	55.5% (43.4%, 66.0%)	59.9% (47.9%, 69.9%)
Month 18	53.6% (41.4%, 64.4%)	59.9% (47.9%, 69.9%)
Month 24	51.3% (38.8%, 62.4%)	57.0% (44.3%, 67.9%)
Month 30	51.3% (38.8%, 62.4%)	57.0% (44.3%, 67.9%)
Month 36	51.3% (38.8%, 62.4%)	57.0% (44.3%, 67.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.94 (0.588, 1.506)	
p-value of 2-sided stratified log-rank test	0.7912	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	37	33
0	17 (45.9%)	17 (51.5%)
1	7 (18.9%)	2 (6.1%)
2	2 (5.4%)	5 (15.2%)
3	8 (21.6%)	1 (3.0%)
>=4	3 (8.1%)	8 (24.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	12 (34.3%)	13 (39.4%)
Censored	23 (65.7%)	20 (60.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.9, NE)	1.4 (0.7, 6.9)
50%	NE (5.6, NE)	NE (2.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	67.6% (49.1%, 80.6%)	61.7% (41.4%, 76.7%)
Month 12	67.6% (49.1%, 80.6%)	57.5% (37.2%, 73.4%)
Month 18	67.6% (49.1%, 80.6%)	53.1% (32.9%, 69.8%)
Month 24	62.8% (43.1%, 77.3%)	53.1% (32.9%, 69.8%)
Month 30	62.8% (43.1%, 77.3%)	53.1% (32.9%, 69.8%)
Month 36	62.8% (43.1%, 77.3%)	53.1% (32.9%, 69.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.56 (0.711, 3.421)	
p-value of 2-sided stratified log-rank test	0.2644	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	12	13
0	9 (75.0%)	4 (30.8%)
1	0	1 (7.7%)
2	0	4 (30.8%)
3	0	0
>=4	3 (25.0%)	4 (30.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	27 (40.3%)	18 (28.1%)
Censored	40 (59.7%)	46 (71.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (0.9, 3.0)	4.1 (1.4, NE)
50%	NE (3.1, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	60.6% (47.2%, 71.6%)	73.5% (60.4%, 82.9%)
Month 12	53.7% (39.8%, 65.8%)	69.4% (55.7%, 79.6%)
Month 18	53.7% (39.8%, 65.8%)	69.4% (55.7%, 79.6%)
Month 24	53.7% (39.8%, 65.8%)	69.4% (55.7%, 79.6%)
Month 30	53.7% (39.8%, 65.8%)	69.4% (55.7%, 79.6%)
Month 36	53.7% (39.8%, 65.8%)	69.4% (55.7%, 79.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.63 (0.345, 1.139)	
p-value of 2-sided stratified log-rank test	0.1191	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	27	18
0	17 (63.0%)	12 (66.7%)
1	2 (7.4%)	1 (5.6%)
2	2 (7.4%)	2 (11.1%)
3	0	0
>=4	6 (22.2%)	3 (16.7%)
p-value from Interaction Test[c]	0.2285	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	52 (57.8%)	41 (47.1%)
Censored	38 (42.2%)	46 (52.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.7 (1.4, 3.5)	2.1 (1.4, 3.5)
50%	7.9 (4.4, 27.8)	26.2 (4.6, NE)
75%	NE (30.1, NE)	NE (38.2, NE)
Survival probability (95% CI) at		
Month 6	56.4% (45.1%, 66.2%)	61.3% (49.9%, 70.9%)
Month 12	44.9% (33.6%, 55.5%)	56.7% (44.9%, 66.8%)
Month 18	43.3% (32.1%, 54.0%)	50.4% (38.0%, 61.5%)
Month 24	39.4% (28.1%, 50.5%)	50.4% (38.0%, 61.5%)
Month 30	36.7% (25.2%, 48.3%)	47.2% (34.2%, 59.1%)
Month 36	28.9% (17.5%, 41.2%)	42.9% (28.8%, 56.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.24 (0.820, 1.862)	
p-value of 2-sided stratified log-rank test	0.3095	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	52	41
0	35 (67.3%)	25 (61.0%)
1	11 (21.2%)	7 (17.1%)
2	2 (3.8%)	2 (4.9%)
3	0	4 (9.8%)
>=4	4 (7.7%)	3 (7.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	20 (57.1%)	19 (57.6%)
Censored	15 (42.9%)	14 (42.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.3 (0.8, 2.8)	1.4 (0.8, 2.4)
50%	4.2 (1.8, NE)	5.4 (2.1, NE)
75%	NE (33.7, NE)	NE (11.1, NE)
Survival probability (95% CI) at		
Month 6	47.8% (30.5%, 63.2%)	50.0% (31.3%, 66.1%)
Month 12	43.4% (26.1%, 59.6%)	42.6% (24.7%, 59.4%)
Month 18	43.4% (26.1%, 59.6%)	42.6% (24.7%, 59.4%)
Month 24	43.4% (26.1%, 59.6%)	42.6% (24.7%, 59.4%)
Month 30	43.4% (26.1%, 59.6%)	38.7% (21.3%, 55.8%)
Month 36	36.2% (17.9%, 54.9%)	31.0% (13.3%, 50.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.05 (0.549, 2.004)	
p-value of 2-sided stratified log-rank test	0.8835	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	20	19
0	12 (60.0%)	16 (84.2%)
1	3 (15.0%)	3 (15.8%)
2	1 (5.0%)	0
3	2 (10.0%)	0
>=4	2 (10.0%)	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	27 (40.3%)	31 (48.4%)
Censored	40 (59.7%)	33 (51.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.7 (2.1, 10.8)	2.9 (1.4, 7.1)
50%	21.7 (10.8, NE)	15.9 (7.1, NE)
75%	41.0 (25.3, NE)	NE (29.4, NE)
Survival probability (95% CI) at		
Month 6	74.9% (61.9%, 84.1%)	66.5% (53.0%, 77.0%)
Month 12	63.5% (48.9%, 75.0%)	52.3% (38.3%, 64.6%)
Month 18	60.9% (45.9%, 72.8%)	46.5% (32.1%, 59.7%)
Month 24	45.8% (29.1%, 61.1%)	46.5% (32.1%, 59.7%)
Month 30	41.2% (24.4%, 57.4%)	37.9% (22.5%, 53.2%)
Month 36	41.2% (24.4%, 57.4%)	37.9% (22.5%, 53.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.84 (0.497, 1.411)	
p-value of 2-sided stratified log-rank test	0.5096	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	27	31
0	17 (63.0%)	23 (74.2%)
1	7 (25.9%)	2 (6.5%)
2	2 (7.4%)	3 (9.7%)
3	1 (3.7%)	1 (3.2%)
>=4	0	2 (6.5%)
p-value from Interaction Test[c]	0.4964	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	71 (78.9%)	71 (81.6%)
Censored	19 (21.1%)	16 (18.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.4, 3.4)	2.1 (1.4, 3.4)
50%	7.3 (4.4, 12.4)	12.6 (5.4, 16.7)
75%	27.8 (19.2, 32.6)	23.1 (18.4, 36.5)
Survival probability (95% CI) at		
Month 6	55.3% (44.2%, 65.0%)	60.1% (48.9%, 69.6%)
Month 12	40.4% (29.9%, 50.7%)	50.1% (39.0%, 60.3%)
Month 18	35.2% (25.1%, 45.5%)	37.6% (27.2%, 47.9%)
Month 24	28.5% (19.1%, 38.6%)	24.8% (16.0%, 34.6%)
Month 30	20.3% (12.2%, 29.9%)	22.2% (13.8%, 31.8%)
Month 36	14.8% (7.9%, 23.7%)	19.0% (11.1%, 28.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.07 (0.765, 1.483)	
p-value of 2-sided stratified log-rank test	0.7062	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	71	71
0	54 (76.1%)	55 (77.5%)
1	11 (15.5%)	7 (9.9%)
2	2 (2.8%)	2 (2.8%)
3	0	4 (5.6%)
>=4	4 (5.6%)	3 (4.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	25 (71.4%)	23 (69.7%)
Censored	10 (28.6%)	10 (30.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.3 (0.8, 2.8)	1.4 (0.8, 2.4)
50%	4.2 (1.8, 16.5)	5.4 (2.1, 31.7)
75%	33.7 (13.0, NE)	34.7 (12.5, NE)
Survival probability (95% CI) at		
Month 6	47.8% (30.5%, 63.2%)	50.0% (31.3%, 66.1%)
Month 12	41.6% (25.1%, 57.4%)	42.9% (25.0%, 59.6%)
Month 18	32.0% (17.1%, 47.9%)	39.3% (22.0%, 56.2%)
Month 24	32.0% (17.1%, 47.9%)	39.3% (22.0%, 56.2%)
Month 30	32.0% (17.1%, 47.9%)	35.7% (19.1%, 52.7%)
Month 36	22.9% (9.6%, 39.5%)	23.0% (9.3%, 40.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.09 (0.612, 1.959)	
p-value of 2-sided stratified log-rank test	0.7578	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	25	23
0	17 (68.0%)	20 (87.0%)
1	3 (12.0%)	3 (13.0%)
2	1 (4.0%)	0
3	2 (8.0%)	0
>=4	2 (8.0%)	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	48 (71.6%)	53 (82.8%)
Censored	19 (28.4%)	11 (17.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.9 (1.4, 6.7)	2.4 (1.4, 4.7)
50%	10.8 (6.8, 18.8)	9.7 (5.6, 13.2)
75%	25.3 (19.5, NE)	25.6 (15.8, 32.9)
Survival probability (95% CI) at		
Month 6	67.0% (54.0%, 77.1%)	62.5% (49.5%, 73.1%)
Month 12	48.7% (35.8%, 60.4%)	40.1% (28.0%, 51.8%)
Month 18	39.8% (27.5%, 51.9%)	28.8% (18.2%, 40.2%)
Month 24	29.4% (18.1%, 41.7%)	25.2% (15.2%, 36.5%)
Month 30	18.9% (9.6%, 30.6%)	16.2% (8.1%, 26.6%)
Month 36	18.9% (9.6%, 30.6%)	14.2% (6.7%, 24.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.89 (0.603, 1.324)	
p-value of 2-sided stratified log-rank test	0.5740	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	48	53
0	38 (79.2%)	45 (84.9%)
1	7 (14.6%)	2 (3.8%)
2	2 (4.2%)	3 (5.7%)
3	1 (2.1%)	1 (1.9%)
>=4	0	2 (3.8%)
p-value from Interaction Test[c]	0.7102	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	39 (43.3%)	34 (39.1%)
Censored	51 (56.7%)	53 (60.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (0.9, 3.0)	2.2 (1.4, 7.2)
50%	NE (4.1, NE)	NE (10.9, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	60.4% (49.2%, 69.9%)	66.9% (55.7%, 75.8%)
Month 12	54.1% (42.5%, 64.3%)	60.5% (48.8%, 70.4%)
Month 18	52.2% (40.4%, 62.7%)	60.5% (48.8%, 70.4%)
Month 24	52.2% (40.4%, 62.7%)	55.0% (42.0%, 66.3%)
Month 30	52.2% (40.4%, 62.7%)	55.0% (42.0%, 66.3%)
Month 36	52.2% (40.4%, 62.7%)	55.0% (42.0%, 66.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.83 (0.524, 1.316)	
p-value of 2-sided stratified log-rank test	0.4345	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	39	34
0	16 (41.0%)	17 (50.0%)
1	7 (17.9%)	6 (17.6%)
2	2 (5.1%)	2 (5.9%)
3	1 (2.6%)	1 (2.9%)
>=4	13 (33.3%)	8 (23.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	11 (31.4%)	14 (42.4%)
Censored	24 (68.6%)	19 (57.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	5.6 (1.0, NE)	1.4 (0.7, 3.2)
50%	NE (16.1, NE)	15.3 (1.5, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	73.3% (54.9%, 85.1%)	54.2% (34.3%, 70.5%)
Month 12	73.3% (54.9%, 85.1%)	54.2% (34.3%, 70.5%)
Month 18	69.2% (50.0%, 82.2%)	49.7% (29.9%, 66.7%)
Month 24	63.9% (43.2%, 78.7%)	49.7% (29.9%, 66.7%)
Month 30	63.9% (43.2%, 78.7%)	49.7% (29.9%, 66.7%)
Month 36	63.9% (43.2%, 78.7%)	49.7% (29.9%, 66.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.80 (0.806, 4.031)	
p-value of 2-sided stratified log-rank test	0.1495	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	11	14
0	6 (54.5%)	5 (35.7%)
1	2 (18.2%)	5 (35.7%)
2	1 (9.1%)	3 (21.4%)
3	1 (9.1%)	0
>=4	1 (9.1%)	1 (7.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	26 (38.8%)	16 (25.0%)
Censored	41 (61.2%)	48 (75.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 3.0)	6.9 (1.4, NE)
50%	NE (3.5, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	60.1% (46.6%, 71.3%)	76.9% (64.0%, 85.6%)
Month 12	58.1% (44.4%, 69.5%)	72.9% (59.5%, 82.5%)
Month 18	58.1% (44.4%, 69.5%)	72.9% (59.5%, 82.5%)
Month 24	58.1% (44.4%, 69.5%)	72.9% (59.5%, 82.5%)
Month 30	58.1% (44.4%, 69.5%)	72.9% (59.5%, 82.5%)
Month 36	53.6% (38.3%, 66.7%)	72.9% (59.5%, 82.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.55 (0.293, 1.020)	
p-value of 2-sided stratified log-rank test	0.0531	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	26	16
0	6 (23.1%)	6 (37.5%)
1	2 (7.7%)	4 (25.0%)
2	2 (7.7%)	1 (6.3%)
3	2 (7.7%)	1 (6.3%)
>=4	14 (53.8%)	4 (25.0%)
p-value from Interaction Test[c]	0.0648	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	69 (76.7%)	57 (65.5%)
Censored	21 (23.3%)	30 (34.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 1.0)
50%	1.4 (0.9, 1.6)	1.8 (1.4, 9.6)
75%	5.5 (2.4, NE)	NE (12.9, NE)
Survival probability (95% CI) at		
Month 6	24.5% (15.9%, 34.0%)	40.8% (30.2%, 51.1%)
Month 12	23.0% (14.6%, 32.5%)	37.1% (26.4%, 47.7%)
Month 18	21.4% (13.2%, 30.9%)	31.3% (20.9%, 42.3%)
Month 24	18.1% (10.4%, 27.5%)	29.1% (18.7%, 40.2%)
Month 30	18.1% (10.4%, 27.5%)	26.4% (16.1%, 37.9%)
Month 36	18.1% (10.4%, 27.5%)	26.4% (16.1%, 37.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.31 (0.920, 1.862)	
p-value of 2-sided stratified log-rank test	0.1424	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	69	57
0	31 (44.9%)	19 (33.3%)
1	13 (18.8%)	8 (14.0%)
2	1 (1.4%)	7 (12.3%)
3	3 (4.3%)	4 (7.0%)
>=4	21 (30.4%)	19 (33.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	30 (85.7%)	18 (54.5%)
Censored	5 (14.3%)	15 (45.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (0.7, 0.8)	0.8 (0.7, 1.4)
50%	0.9 (0.8, 1.6)	2.7 (0.8, NE)
75%	2.0 (1.1, NE)	NE (4.1, NE)
Survival probability (95% CI) at		
Month 6	15.2% (5.6%, 29.3%)	42.6% (24.7%, 59.4%)
Month 12	12.2% (3.9%, 25.6%)	42.6% (24.7%, 59.4%)
Month 18	12.2% (3.9%, 25.6%)	42.6% (24.7%, 59.4%)
Month 24	12.2% (3.9%, 25.6%)	42.6% (24.7%, 59.4%)
Month 30	12.2% (3.9%, 25.6%)	42.6% (24.7%, 59.4%)
Month 36	12.2% (3.9%, 25.6%)	37.8% (20.3%, 55.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	2.00 (1.090, 3.681)	
p-value of 2-sided stratified log-rank test	0.0183	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	30	18
0	13 (43.3%)	7 (38.9%)
1	1 (3.3%)	2 (11.1%)
2	4 (13.3%)	3 (16.7%)
3	0	0
>=4	12 (40.0%)	6 (33.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	43 (64.2%)	44 (68.8%)
Censored	24 (35.8%)	20 (31.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 0.9)
50%	1.5 (0.9, 4.4)	1.4 (0.9, 2.1)
75%	25.3 (4.4, NE)	20.6 (2.1, NE)
Survival probability (95% CI) at		
Month 6	36.9% (24.8%, 49.0%)	31.1% (19.9%, 42.9%)
Month 12	32.2% (20.5%, 44.6%)	31.1% (19.9%, 42.9%)
Month 18	29.0% (17.2%, 41.9%)	28.0% (16.8%, 40.3%)
Month 24	29.0% (17.2%, 41.9%)	24.0% (12.7%, 37.2%)
Month 30	19.9% (8.4%, 34.8%)	24.0% (12.7%, 37.2%)
Month 36	19.9% (8.4%, 34.8%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.86 (0.564, 1.324)	
p-value of 2-sided stratified log-rank test	0.5106	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	43	44
0	18 (41.9%)	20 (45.5%)
1	5 (11.6%)	3 (6.8%)
2	2 (4.7%)	2 (4.5%)
3	3 (7.0%)	3 (6.8%)
>=4	15 (34.9%)	16 (36.4%)
p-value from Interaction Test[c]	0.0285	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	79 (87.8%)	74 (85.1%)
Censored	11 (12.2%)	13 (14.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 1.0)
50%	1.4 (0.9, 2.1)	1.8 (1.4, 4.2)
75%	6.2 (3.0, 19.6)	16.7 (9.8, 21.5)
Survival probability (95% CI) at		
Month 6	25.4% (16.8%, 34.8%)	39.1% (28.8%, 49.3%)
Month 12	19.3% (11.8%, 28.3%)	31.8% (22.2%, 41.8%)
Month 18	18.1% (10.8%, 26.9%)	20.8% (12.8%, 30.0%)
Month 24	13.3% (7.1%, 21.4%)	14.5% (7.9%, 23.0%)
Month 30	9.7% (4.5%, 17.1%)	13.2% (6.9%, 21.5%)
Month 36	9.7% (4.5%, 17.1%)	13.2% (6.9%, 21.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.20 (0.872, 1.656)	
p-value of 2-sided stratified log-rank test	0.2808	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	79	74
0	41 (51.9%)	36 (48.6%)
1	13 (16.5%)	8 (10.8%)
2	1 (1.3%)	7 (9.5%)
3	3 (3.8%)	4 (5.4%)
>=4	21 (26.6%)	19 (25.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	31 (88.6%)	22 (66.7%)
Censored	4 (11.4%)	11 (33.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (0.7, 0.8)	0.8 (0.7, 1.4)
50%	0.9 (0.8, 1.6)	2.7 (0.8, 31.3)
75%	2.0 (1.1, 27.6)	39.1 (4.6, NE)
Survival probability (95% CI) at		
Month 6	15.2% (5.6%, 29.3%)	40.0% (22.8%, 56.7%)
Month 12	12.2% (3.9%, 25.6%)	40.0% (22.8%, 56.7%)
Month 18	12.2% (3.9%, 25.6%)	40.0% (22.8%, 56.7%)
Month 24	12.2% (3.9%, 25.6%)	36.7% (20.1%, 53.4%)
Month 30	8.1% (1.7%, 21.3%)	36.7% (20.1%, 53.4%)
Month 36	8.1% (1.7%, 21.3%)	29.3% (14.4%, 46.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.96 (1.092, 3.507)	
p-value of 2-sided stratified log-rank test	0.0179	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	31	22
0	14 (45.2%)	11 (50.0%)
1	1 (3.2%)	2 (9.1%)
2	4 (12.9%)	3 (13.6%)
3	0	0
>=4	12 (38.7%)	6 (27.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	58 (86.6%)	58 (90.6%)
Censored	9 (13.4%)	6 (9.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 0.8)
50%	1.5 (0.9, 3.5)	1.4 (0.9, 2.1)
75%	9.8 (3.6, 25.3)	11.7 (2.1, 20.6)
Survival probability (95% CI) at		
Month 6	31.0% (20.2%, 42.5%)	29.7% (19.1%, 41.1%)
Month 12	23.9% (14.1%, 35.1%)	25.0% (15.2%, 36.0%)
Month 18	18.4% (9.8%, 29.2%)	16.8% (8.8%, 27.0%)
Month 24	16.6% (8.4%, 27.1%)	13.1% (6.1%, 22.9%)
Month 30	7.4% (2.4%, 16.1%)	9.3% (3.6%, 18.5%)
Month 36	7.4% (2.4%, 16.1%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.90 (0.625, 1.309)	
p-value of 2-sided stratified log-rank test	0.6104	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	58	58
0	33 (56.9%)	34 (58.6%)
1	5 (8.6%)	3 (5.2%)
2	2 (3.4%)	2 (3.4%)
3	3 (5.2%)	3 (5.2%)
>=4	15 (25.9%)	16 (27.6%)
p-value from Interaction Test[c]	0.0133	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	28 (31.1%)	21 (24.1%)
Censored	62 (68.9%)	66 (75.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	13.1 (2.1, 21.8)	9.2 (1.4, NE)
50%	NE (27.9, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	79.9% (69.6%, 87.0%)	78.7% (68.3%, 86.0%)
Month 12	76.9% (66.1%, 84.7%)	74.3% (63.3%, 82.5%)
Month 18	68.8% (56.9%, 78.1%)	74.3% (63.3%, 82.5%)
Month 24	64.9% (52.3%, 74.9%)	74.3% (63.3%, 82.5%)
Month 30	62.3% (49.2%, 72.9%)	74.3% (63.3%, 82.5%)
Month 36	58.6% (44.3%, 70.5%)	74.3% (63.3%, 82.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.80 (0.455, 1.413)	
p-value of 2-sided stratified log-rank test	0.4377	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	28	21
0	17 (60.7%)	11 (52.4%)
1	5 (17.9%)	1 (4.8%)
2	3 (10.7%)	1 (4.8%)
3	1 (3.6%)	4 (19.0%)
>=4	2 (7.1%)	4 (19.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	4 (11.4%)	10 (30.3%)
Censored	31 (88.6%)	23 (69.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (20.0, NE)	5.6 (0.9, NE)
50%	NE (NE, NE)	NE (7.2, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	91.2% (75.2%, 97.1%)	74.7% (53.8%, 87.1%)
Month 12	91.2% (75.2%, 97.1%)	66.4% (45.0%, 81.0%)
Month 18	91.2% (75.2%, 97.1%)	62.2% (40.8%, 77.8%)
Month 24	87.1% (68.7%, 95.0%)	62.2% (40.8%, 77.8%)
Month 30	87.1% (68.7%, 95.0%)	62.2% (40.8%, 77.8%)
Month 36	87.1% (68.7%, 95.0%)	62.2% (40.8%, 77.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	3.69 (1.156, 11.799)	
p-value of 2-sided stratified log-rank test	0.0180	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	4	10
0	2 (50.0%)	6 (60.0%)
1	0	2 (20.0%)
2	1 (25.0%)	0
3	1 (25.0%)	0
>=4	0	2 (20.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	13 (19.4%)	15 (23.4%)
Censored	54 (80.6%)	49 (76.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	21.0 (2.1, NE)	19.9 (2.1, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	81.4% (68.8%, 89.3%)	80.0% (67.5%, 88.1%)
Month 12	81.4% (68.8%, 89.3%)	75.3% (61.6%, 84.7%)
Month 18	78.4% (64.5%, 87.3%)	75.3% (61.6%, 84.7%)
Month 24	74.2% (58.1%, 84.9%)	71.4% (55.7%, 82.3%)
Month 30	74.2% (58.1%, 84.9%)	71.4% (55.7%, 82.3%)
Month 36	74.2% (58.1%, 84.9%)	71.4% (55.7%, 82.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.10 (0.524, 2.314)	
p-value of 2-sided stratified log-rank test	0.7987	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	13	15
0	2 (15.4%)	7 (46.7%)
1	3 (23.1%)	3 (20.0%)
2	2 (15.4%)	2 (13.3%)
3	0	0
>=4	6 (46.2%)	3 (20.0%)
p-value from Interaction Test[c]	0.0838	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	10 (11.1%)	12 (13.8%)
Censored	80 (88.9%)	75 (86.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (1.4, NE)	6.5 (2.3, NE)
50%	NE (NE, NE)	NE (8.5, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	80.9% (66.4%, 89.6%)	75.6% (57.9%, 86.6%)
Month 12	78.0% (62.7%, 87.6%)	62.2% (41.7%, 77.3%)
Month 18	78.0% (62.7%, 87.6%)	62.2% (41.7%, 77.3%)
Month 24	78.0% (62.7%, 87.6%)	62.2% (41.7%, 77.3%)
Month 30	78.0% (62.7%, 87.6%)	62.2% (41.7%, 77.3%)
Month 36	78.0% (62.7%, 87.6%)	62.2% (41.7%, 77.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.65 (0.276, 1.539)	
p-value of 2-sided stratified log-rank test	0.3256	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	10	12
0	4 (40.0%)	6 (50.0%)
1	4 (40.0%)	3 (25.0%)
2	1 (10.0%)	1 (8.3%)
3	1 (10.0%)	1 (8.3%)
>=4	0	1 (8.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	2 (5.7%)	0
Censored	33 (94.3%)	33 (100%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (1.4, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	89.4% (63.8%, 97.3%)	100% (100%, 100%)
Month 12	89.4% (63.8%, 97.3%)	100% (100%, 100%)
Month 18	89.4% (63.8%, 97.3%)	100% (100%, 100%)
Month 24	89.4% (63.8%, 97.3%)	100% (100%, 100%)
Month 30	89.4% (63.8%, 97.3%)	100% (100%, 100%)
Month 36	89.4% (63.8%, 97.3%)	100% (100%, 100%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	- (-, -)	
p-value of 2-sided stratified log-rank test	0.1748	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	2	0
0	0	0
1	2 (100%)	0
2	0	0
3	0	0
>=4	0	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	5 (7.5%)	1 (1.6%)
Censored	62 (92.5%)	63 (98.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (0.7, NE)	NE (1.6, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	87.2% (65.3%, 95.7%)	95.8% (73.9%, 99.4%)
Month 12	76.5% (51.8%, 89.7%)	95.8% (73.9%, 99.4%)
Month 18	76.5% (51.8%, 89.7%)	95.8% (73.9%, 99.4%)
Month 24	76.5% (51.8%, 89.7%)	95.8% (73.9%, 99.4%)
Month 30	76.5% (51.8%, 89.7%)	95.8% (73.9%, 99.4%)
Month 36	76.5% (51.8%, 89.7%)	95.8% (73.9%, 99.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	5.30 (0.619, 45.368)	
p-value of 2-sided stratified log-rank test	0.0884	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	5	1
0	3 (60.0%)	1 (100%)
1	0	0
2	1 (20.0%)	0
3	0	0
>=4	1 (20.0%)	0
p-value from Interaction Test[c]	0.2174	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	46 (51.1%)	58 (66.7%)
Censored	44 (48.9%)	29 (33.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	8.0 (2.9, 14.9)	8.5 (4.1, 10.8)
50%	21.1 (16.8, 29.7)	16.0 (12.0, 18.2)
75%	32.6 (29.7, NE)	22.2 (18.4, 32.4)
Survival probability (95% CI) at		
Month 6	81.4% (70.1%, 88.8%)	80.9% (69.4%, 88.5%)
Month 12	67.3% (54.6%, 77.2%)	62.4% (49.6%, 72.8%)
Month 18	60.4% (47.3%, 71.2%)	39.0% (27.0%, 50.9%)
Month 24	49.7% (36.7%, 61.5%)	20.4% (11.3%, 31.3%)
Month 30	33.7% (21.7%, 46.2%)	15.1% (7.4%, 25.3%)
Month 36	23.7% (12.9%, 36.5%)	12.9% (5.8%, 23.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.62 (0.415, 0.921)	
p-value of 2-sided stratified log-rank test	0.0173	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	46	58
0	40 (87.0%)	52 (89.7%)
1	4 (8.7%)	3 (5.2%)
2	1 (2.2%)	1 (1.7%)
3	1 (2.2%)	1 (1.7%)
>=4	0	1 (1.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	14 (40.0%)	11 (33.3%)
Censored	21 (60.0%)	22 (66.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	20.3 (2.8, 28.6)	13.6 (3.8, 34.7)
50%	30.7 (22.4, 37.6)	36.1 (13.6, NE)
75%	NE (30.7, NE)	NE (36.1, NE)
Survival probability (95% CI) at		
Month 6	92.1% (72.1%, 98.0%)	90.7% (67.6%, 97.6%)
Month 12	88.0% (67.1%, 96.0%)	85.6% (61.7%, 95.1%)
Month 18	79.2% (56.8%, 90.8%)	74.9% (49.7%, 88.8%)
Month 24	69.5% (46.2%, 84.3%)	69.2% (43.5%, 84.9%)
Month 30	53.5% (30.3%, 72.1%)	69.2% (43.5%, 84.9%)
Month 36	34.7% (14.3%, 56.1%)	54.5% (28.1%, 74.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.25 (0.562, 2.784)	
p-value of 2-sided stratified log-rank test	0.5830	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	14	11
0	12 (85.7%)	11 (100%)
1	2 (14.3%)	0
2	0	0
3	0	0
>=4	0	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	34 (50.7%)	42 (65.6%)
Censored	33 (49.3%)	22 (34.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	6.8 (3.6, 9.5)	10.2 (6.0, 13.2)
50%	13.4 (8.4, 23.2)	16.1 (13.2, 22.1)
75%	25.8 (19.5, NE)	28.2 (22.0, 35.5)
Survival probability (95% CI) at		
Month 6	79.0% (64.5%, 88.1%)	88.7% (76.5%, 94.8%)
Month 12	55.7% (40.0%, 68.9%)	67.0% (52.4%, 78.1%)
Month 18	45.6% (30.3%, 59.6%)	44.4% (30.4%, 57.6%)
Month 24	34.2% (20.1%, 48.9%)	35.3% (22.1%, 48.7%)
Month 30	16.8% (6.3%, 31.7%)	21.2% (10.7%, 34.0%)
Month 36	16.8% (6.3%, 31.7%)	9.5% (2.8%, 21.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.17 (0.743, 1.845)	
p-value of 2-sided stratified log-rank test	0.4998	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	34	42
0	32 (94.1%)	42 (100%)
1	0	0
2	1 (2.9%)	0
3	0	0
>=4	1 (2.9%)	0
p-value from Interaction Test[c]	0.0994	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	8 (8.9%)	4 (4.6%)
Censored	82 (91.1%)	83 (95.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (5.8, NE)	NE (27.7, NE)
50%	NE (NE, NE)	NE (27.7, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	88.4% (74.1%, 95.0%)	92.0% (77.1%, 97.3%)
Month 12	81.9% (65.1%, 91.1%)	92.0% (77.1%, 97.3%)
Month 18	78.3% (60.5%, 88.8%)	92.0% (77.1%, 97.3%)
Month 24	78.3% (60.5%, 88.8%)	92.0% (77.1%, 97.3%)
Month 30	78.3% (60.5%, 88.8%)	80.5% (45.7%, 94.1%)
Month 36	78.3% (60.5%, 88.8%)	80.5% (45.7%, 94.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.76 (0.226, 2.537)	
p-value of 2-sided stratified log-rank test	0.6491	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	8	4
0	2 (25.0%)	1 (25.0%)
1	2 (25.0%)	1 (25.0%)
2	3 (37.5%)	0
3	1 (12.5%)	0
>=4	0	2 (50.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	2 (5.7%)	0
Censored	33 (94.3%)	33 (100%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (0.7, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	95.2% (70.7%, 99.3%)	100% (100%, 100%)
Month 12	88.4% (60.3%, 97.1%)	100% (100%, 100%)
Month 18	88.4% (60.3%, 97.1%)	100% (100%, 100%)
Month 24	88.4% (60.3%, 97.1%)	100% (100%, 100%)
Month 30	88.4% (60.3%, 97.1%)	100% (100%, 100%)
Month 36	88.4% (60.3%, 97.1%)	100% (100%, 100%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	- (-, -)	
p-value of 2-sided stratified log-rank test	0.2104	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	2	0
0	2 (100%)	0
1	0	0
2	0	0
3	0	0
>=4	0	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	1 (1.5%)	3 (4.7%)
Censored	66 (98.5%)	61 (95.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (2.1, NE)	NE (1.4, NE)
50%	NE (NE, NE)	NE (25.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	95.8% (73.9%, 99.4%)	91.8% (71.1%, 97.9%)
Month 12	95.8% (73.9%, 99.4%)	91.8% (71.1%, 97.9%)
Month 18	95.8% (73.9%, 99.4%)	91.8% (71.1%, 97.9%)
Month 24	95.8% (73.9%, 99.4%)	91.8% (71.1%, 97.9%)
Month 30	95.8% (73.9%, 99.4%)	76.5% (33.5%, 93.7%)
Month 36	95.8% (73.9%, 99.4%)	76.5% (33.5%, 93.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	3.03 (0.314, 29.142)	
p-value of 2-sided stratified log-rank test	0.3137	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	1	3
0	0	3 (100%)
1	0	0
2	0	0
3	0	0
>=4	1 (100%)	0
p-value from Interaction Test[c]	0.5319	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	44 (48.9%)	51 (58.6%)
Censored	46 (51.1%)	36 (41.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 3.4)	2.8 (1.4, 4.5)
50%	12.8 (5.0, NE)	12.9 (5.9, 20.8)
75%	NE (NE, NE)	34.3 (20.8, NE)
Survival probability (95% CI) at		
Month 6	56.4% (45.1%, 66.3%)	61.1% (49.7%, 70.8%)
Month 12	50.2% (38.7%, 60.6%)	51.8% (40.0%, 62.4%)
Month 18	48.4% (36.9%, 59.1%)	41.2% (29.3%, 52.6%)
Month 24	44.0% (32.1%, 55.3%)	33.9% (22.1%, 46.1%)
Month 30	44.0% (32.1%, 55.3%)	31.3% (19.6%, 43.7%)
Month 36	44.0% (32.1%, 55.3%)	24.6% (13.2%, 37.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.86 (0.573, 1.288)	
p-value of 2-sided stratified log-rank test	0.4550	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	44	51
0	27 (61.4%)	30 (58.8%)
1	5 (11.4%)	12 (23.5%)
2	4 (9.1%)	1 (2.0%)
3	2 (4.5%)	4 (7.8%)
>=4	6 (13.6%)	4 (7.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	17 (48.6%)	20 (60.6%)
Censored	18 (51.4%)	13 (39.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.4 (0.8, 15.6)	2.1 (0.8, 3.3)
50%	22.5 (6.9, NE)	9.9 (2.2, 25.6)
75%	NE (NE, NE)	NE (14.1, NE)
Survival probability (95% CI) at		
Month 6	74.3% (56.4%, 85.7%)	55.4% (35.7%, 71.3%)
Month 12	62.5% (44.3%, 76.2%)	47.5% (28.3%, 64.4%)
Month 18	59.0% (40.7%, 73.4%)	43.5% (24.9%, 60.8%)
Month 24	48.1% (30.0%, 64.2%)	35.6% (18.4%, 53.3%)
Month 30	48.1% (30.0%, 64.2%)	31.7% (15.4%, 49.3%)
Month 36	48.1% (30.0%, 64.2%)	26.4% (11.1%, 44.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.67 (0.346, 1.307)	
p-value of 2-sided stratified log-rank test	0.2419	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	17	20
0	11 (64.7%)	15 (75.0%)
1	1 (5.9%)	2 (10.0%)
2	1 (5.9%)	0
3	2 (11.8%)	0
>=4	2 (11.8%)	3 (15.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	38 (56.7%)	31 (48.4%)
Censored	29 (43.3%)	33 (51.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.2 (0.8, 5.6)	2.9 (1.0, 7.6)
50%	10.8 (5.6, 17.6)	17.8 (7.6, 34.1)
75%	37.2 (15.0, NE)	NE (32.2, NE)
Survival probability (95% CI) at		
Month 6	57.0% (43.1%, 68.7%)	65.1% (51.5%, 75.7%)
Month 12	45.1% (31.0%, 58.2%)	59.0% (45.1%, 70.5%)
Month 18	34.8% (21.4%, 48.5%)	48.3% (33.7%, 61.5%)
Month 24	32.1% (19.0%, 45.9%)	48.3% (33.7%, 61.5%)
Month 30	28.9% (16.1%, 42.9%)	43.0% (26.9%, 58.1%)
Month 36	28.9% (16.1%, 42.9%)	26.9% (9.5%, 48.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.39 (0.857, 2.250)	
p-value of 2-sided stratified log-rank test	0.1801	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	38	31
0	25 (65.8%)	22 (71.0%)
1	6 (15.8%)	4 (12.9%)
2	1 (2.6%)	3 (9.7%)
3	4 (10.5%)	1 (3.2%)
>=4	2 (5.3%)	1 (3.2%)
p-value from Interaction Test[c]	0.1052	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	67 (74.4%)	73 (83.9%)
Censored	23 (25.6%)	14 (16.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.9, 3.0)	2.8 (1.4, 4.5)
50%	6.9 (4.4, 12.4)	11.8 (6.9, 14.8)
75%	30.2 (18.7, NE)	20.8 (16.3, 31.3)
Survival probability (95% CI) at		
Month 6	52.9% (41.9%, 62.8%)	61.2% (50.1%, 70.7%)
Month 12	40.5% (30.0%, 50.7%)	48.7% (37.7%, 58.9%)
Month 18	36.6% (26.3%, 46.8%)	31.0% (21.3%, 41.2%)
Month 24	28.7% (19.3%, 38.8%)	19.4% (11.5%, 28.7%)
Month 30	26.1% (17.1%, 36.0%)	16.8% (9.5%, 25.8%)
Month 36	21.2% (12.8%, 31.1%)	12.2% (6.0%, 20.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.93 (0.666, 1.298)	
p-value of 2-sided stratified log-rank test	0.6667	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	67	73
0	50 (74.6%)	52 (71.2%)
1	5 (7.5%)	12 (16.4%)
2	4 (6.0%)	1 (1.4%)
3	2 (3.0%)	4 (5.5%)
>=4	6 (9.0%)	4 (5.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	24 (68.6%)	25 (75.8%)
Censored	11 (31.4%)	8 (24.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.4 (0.8, 13.2)	2.1 (0.8, 3.3)
50%	21.8 (6.9, 30.7)	6.2 (2.2, 23.3)
75%	NE (27.6, NE)	32.7 (14.1, NE)
Survival probability (95% CI) at		
Month 6	74.3% (56.4%, 85.7%)	50.0% (31.3%, 66.1%)
Month 12	62.9% (44.8%, 76.5%)	43.3% (25.6%, 59.9%)
Month 18	56.6% (38.5%, 71.2%)	40.0% (22.8%, 56.7%)
Month 24	44.0% (27.0%, 59.8%)	30.0% (15.0%, 46.6%)
Month 30	37.7% (21.7%, 53.7%)	26.7% (12.6%, 43.0%)
Month 36	27.0% (13.0%, 43.2%)	18.3% (6.6%, 34.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.74 (0.415, 1.310)	
p-value of 2-sided stratified log-rank test	0.3008	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	24	25
0	18 (75.0%)	20 (80.0%)
1	1 (4.2%)	2 (8.0%)
2	1 (4.2%)	0
3	2 (8.3%)	0
>=4	2 (8.3%)	3 (12.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	54 (80.6%)	52 (81.3%)
Censored	13 (19.4%)	12 (18.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 3.5)	2.3 (0.9, 5.6)
50%	6.1 (3.7, 8.4)	11.0 (5.8, 15.9)
75%	15.3 (9.5, 37.2)	24.6 (16.1, 34.1)
Survival probability (95% CI) at		
Month 6	50.9% (38.0%, 62.4%)	62.5% (49.5%, 73.1%)
Month 12	32.3% (21.0%, 44.1%)	48.1% (35.4%, 59.7%)
Month 18	22.1% (12.6%, 33.2%)	30.2% (19.4%, 41.8%)
Month 24	18.7% (10.0%, 29.4%)	26.5% (16.1%, 37.9%)
Month 30	15.3% (7.6%, 25.5%)	18.0% (9.2%, 29.2%)
Month 36	15.3% (7.6%, 25.5%)	11.3% (3.8%, 23.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.27 (0.864, 1.869)	
p-value of 2-sided stratified log-rank test	0.2254	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	54	52
0	41 (75.9%)	43 (82.7%)
1	6 (11.1%)	4 (7.7%)
2	1 (1.9%)	3 (5.8%)
3	4 (7.4%)	1 (1.9%)
>=4	2 (3.7%)	1 (1.9%)
p-value from Interaction Test[c]	0.2026	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	47 (52.2%)	37 (42.5%)
Censored	43 (47.8%)	50 (57.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.0 (0.8, 1.4)
50%	4.1 (1.6, NE)	NE (2.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	49.0% (38.1%, 59.1%)	57.8% (46.5%, 67.4%)
Month 12	49.0% (38.1%, 59.1%)	56.3% (45.0%, 66.1%)
Month 18	47.4% (36.4%, 57.6%)	56.3% (45.0%, 66.1%)
Month 24	43.1% (31.7%, 54.0%)	56.3% (45.0%, 66.1%)
Month 30	43.1% (31.7%, 54.0%)	56.3% (45.0%, 66.1%)
Month 36	43.1% (31.7%, 54.0%)	56.3% (45.0%, 66.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.81 (0.523, 1.240)	
p-value of 2-sided stratified log-rank test	0.3137	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	47	37
0	11 (23.4%)	11 (29.7%)
1	12 (25.5%)	6 (16.2%)
2	4 (8.5%)	1 (2.7%)
3	7 (14.9%)	5 (13.5%)
>=4	13 (27.7%)	14 (37.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	16 (45.7%)	15 (45.5%)
Censored	19 (54.3%)	18 (54.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.3)	0.9 (0.7, 1.6)
50%	NE (1.6, NE)	3.5 (1.4, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	56.2% (38.2%, 70.9%)	48.2% (29.2%, 64.8%)
Month 12	56.2% (38.2%, 70.9%)	48.2% (29.2%, 64.8%)
Month 18	52.2% (34.0%, 67.6%)	48.2% (29.2%, 64.8%)
Month 24	52.2% (34.0%, 67.6%)	48.2% (29.2%, 64.8%)
Month 30	52.2% (34.0%, 67.6%)	48.2% (29.2%, 64.8%)
Month 36	52.2% (34.0%, 67.6%)	48.2% (29.2%, 64.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.25 (0.611, 2.569)	
p-value of 2-sided stratified log-rank test	0.5731	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	16	15
0	5 (31.3%)	7 (46.7%)
1	2 (12.5%)	2 (13.3%)
2	0	1 (6.7%)
3	2 (12.5%)	2 (13.3%)
>=4	7 (43.8%)	3 (20.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	31 (46.3%)	23 (35.9%)
Censored	36 (53.7%)	41 (64.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.4)	1.5 (0.8, 3.6)
50%	9.1 (2.4, NE)	NE (5.6, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	51.3% (37.9%, 63.2%)	61.9% (48.4%, 72.9%)
Month 12	49.1% (35.7%, 61.2%)	61.9% (48.4%, 72.9%)
Month 18	45.8% (31.9%, 58.7%)	61.9% (48.4%, 72.9%)
Month 24	45.8% (31.9%, 58.7%)	61.9% (48.4%, 72.9%)
Month 30	45.8% (31.9%, 58.7%)	61.9% (48.4%, 72.9%)
Month 36	45.8% (31.9%, 58.7%)	61.9% (48.4%, 72.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.69 (0.400, 1.178)	
p-value of 2-sided stratified log-rank test	0.1692	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	31	23
0	12 (38.7%)	3 (13.0%)
1	4 (12.9%)	6 (26.1%)
2	1 (3.2%)	3 (13.0%)
3	3 (9.7%)	1 (4.3%)
>=4	11 (35.5%)	10 (43.5%)
p-value from Interaction Test[c]	0.3920	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	68 (75.6%)	72 (82.8%)
Censored	22 (24.4%)	15 (17.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.4)	0.9 (0.8, 1.4)
50%	1.6 (1.4, 2.1)	1.5 (1.4, 2.1)
75%	4.2 (2.7, NE)	3.7 (2.8, 8.3)
Survival probability (95% CI) at		
Month 6	24.7% (16.2%, 34.2%)	17.6% (10.3%, 26.6%)
Month 12	22.0% (13.8%, 31.4%)	12.1% (5.2%, 22.1%)
Month 18	22.0% (13.8%, 31.4%)	12.1% (5.2%, 22.1%)
Month 24	22.0% (13.8%, 31.4%)	12.1% (5.2%, 22.1%)
Month 30	22.0% (13.8%, 31.4%)	12.1% (5.2%, 22.1%)
Month 36	22.0% (13.8%, 31.4%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.89 (0.636, 1.250)	
p-value of 2-sided stratified log-rank test	0.4937	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	68	72
0	20 (29.4%)	28 (38.9%)
1	5 (7.4%)	4 (5.6%)
2	7 (10.3%)	5 (6.9%)
3	2 (2.9%)	2 (2.8%)
>=4	34 (50.0%)	33 (45.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	31 (88.6%)	26 (78.8%)
Censored	4 (11.4%)	7 (21.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 1.4)	0.8 (0.7, 1.4)
50%	1.6 (1.1, 2.1)	1.4 (0.8, 2.2)
75%	2.8 (2.1, 5.6)	2.8 (1.4, 3.9)
Survival probability (95% CI) at		
Month 6	11.4% (3.6%, 24.2%)	10.4% (2.7%, 24.5%)
Month 12	11.4% (3.6%, 24.2%)	10.4% (2.7%, 24.5%)
Month 18	11.4% (3.6%, 24.2%)	10.4% (2.7%, 24.5%)
Month 24	11.4% (3.6%, 24.2%)	10.4% (2.7%, 24.5%)
Month 30	11.4% (3.6%, 24.2%)	10.4% (2.7%, 24.5%)
Month 36	NE (NE, NE)	10.4% (2.7%, 24.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.87 (0.509, 1.483)	
p-value of 2-sided stratified log-rank test	0.6545	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	31	26
0	8 (25.8%)	9 (34.6%)
1	0	1 (3.8%)
2	1 (3.2%)	1 (3.8%)
3	2 (6.5%)	3 (11.5%)
>=4	20 (64.5%)	12 (46.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	52 (77.6%)	47 (73.4%)
Censored	15 (22.4%)	17 (26.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.0)	0.8 (0.7, 1.4)
50%	1.5 (1.1, 2.1)	1.5 (1.4, 2.3)
75%	3.0 (2.1, 9.1)	8.0 (2.6, NE)
Survival probability (95% CI) at		
Month 6	19.7% (10.8%, 30.4%)	27.0% (16.4%, 38.7%)
Month 12	12.5% (5.2%, 23.1%)	22.6% (12.7%, 34.3%)
Month 18	12.5% (5.2%, 23.1%)	22.6% (12.7%, 34.3%)
Month 24	12.5% (5.2%, 23.1%)	18.1% (8.1%, 31.2%)
Month 30	NE (NE, NE)	18.1% (8.1%, 31.2%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.20 (0.803, 1.784)	
p-value of 2-sided stratified log-rank test	0.3688	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	52	47
0	10 (19.2%)	13 (27.7%)
1	2 (3.8%)	3 (6.4%)
2	9 (17.3%)	5 (10.6%)
3	2 (3.8%)	1 (2.1%)
>=4	29 (55.8%)	25 (53.2%)
p-value from Interaction Test[c]	0.5234	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	80 (88.9%)	83 (95.4%)
Censored	10 (11.1%)	4 (4.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 1.4)	0.9 (0.8, 1.4)
50%	1.6 (1.4, 2.2)	1.5 (1.4, 2.1)
75%	4.2 (2.8, 21.1)	3.7 (2.8, 8.2)
Survival probability (95% CI) at		
Month 6	23.6% (15.4%, 32.8%)	17.4% (10.3%, 26.1%)
Month 12	19.1% (11.7%, 27.8%)	10.2% (4.7%, 18.1%)
Month 18	17.9% (10.8%, 26.5%)	5.8% (2.0%, 12.8%)
Month 24	15.3% (8.7%, 23.7%)	1.5% (0.1%, 6.9%)
Month 30	11.5% (5.8%, 19.3%)	1.5% (0.1%, 6.9%)
Month 36	11.5% (5.8%, 19.3%)	1.5% (0.1%, 6.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.79 (0.574, 1.085)	
p-value of 2-sided stratified log-rank test	0.1371	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	80	83
0	32 (40.0%)	39 (47.0%)
1	5 (6.3%)	4 (4.8%)
2	7 (8.8%)	5 (6.0%)
3	2 (2.5%)	2 (2.4%)
>=4	34 (42.5%)	33 (39.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	34 (97.1%)	27 (81.8%)
Censored	1 (2.9%)	6 (18.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 1.4)	0.8 (0.7, 1.4)
50%	1.6 (1.1, 2.1)	1.4 (0.8, 2.2)
75%	2.8 (2.1, 5.6)	2.8 (1.4, 3.9)
Survival probability (95% CI) at		
Month 6	11.4% (3.6%, 24.2%)	10.4% (2.7%, 24.5%)
Month 12	11.4% (3.6%, 24.2%)	10.4% (2.7%, 24.5%)
Month 18	5.7% (1.0%, 16.7%)	10.4% (2.7%, 24.5%)
Month 24	5.7% (1.0%, 16.7%)	10.4% (2.7%, 24.5%)
Month 30	2.9% (0.2%, 12.7%)	10.4% (2.7%, 24.5%)
Month 36	NE (NE, NE)	10.4% (2.7%, 24.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.98 (0.577, 1.650)	
p-value of 2-sided stratified log-rank test	0.9897	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	34	27
0	11 (32.4%)	10 (37.0%)
1	0	1 (3.7%)
2	1 (2.9%)	1 (3.7%)
3	2 (5.9%)	3 (11.1%)
>=4	20 (58.8%)	12 (44.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	63 (94.0%)	59 (92.2%)
Censored	4 (6.0%)	5 (7.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.0)	0.8 (0.7, 1.0)
50%	1.5 (1.1, 2.1)	1.6 (1.4, 2.6)
75%	3.3 (2.1, 7.7)	7.0 (2.8, 16.1)
Survival probability (95% CI) at		
Month 6	17.2% (9.2%, 27.3%)	26.6% (16.5%, 37.7%)
Month 12	8.7% (3.3%, 17.4%)	18.8% (10.3%, 29.1%)
Month 18	6.9% (2.3%, 15.2%)	12.3% (5.7%, 21.7%)
Month 24	5.2% (1.4%, 12.9%)	8.2% (2.9%, 17.1%)
Month 30	0 (NE, NE)	5.5% (1.3%, 14.4%)
Month 36	0 (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.29 (0.896, 1.844)	
p-value of 2-sided stratified log-rank test	0.1649	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	63	59
0	21 (33.3%)	25 (42.4%)
1	2 (3.2%)	3 (5.1%)
2	9 (14.3%)	5 (8.5%)
3	2 (3.2%)	1 (1.7%)
>=4	29 (46.0%)	25 (42.4%)
p-value from Interaction Test[c]	0.1517	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	20 (22.2%)	14 (16.1%)
Censored	70 (77.8%)	73 (83.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	23.0 (4.2, NE)	NE (5.6, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	83.8% (74.1%, 90.0%)	84.2% (74.3%, 90.5%)
Month 12	80.6% (70.2%, 87.7%)	84.2% (74.3%, 90.5%)
Month 18	78.9% (68.0%, 86.4%)	84.2% (74.3%, 90.5%)
Month 24	74.6% (62.5%, 83.4%)	84.2% (74.3%, 90.5%)
Month 30	72.0% (59.0%, 81.5%)	84.2% (74.3%, 90.5%)
Month 36	72.0% (59.0%, 81.5%)	84.2% (74.3%, 90.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.74 (0.373, 1.463)	
p-value of 2-sided stratified log-rank test	0.3821	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	20	14
0	11 (55.0%)	9 (64.3%)
1	4 (20.0%)	3 (21.4%)
2	2 (10.0%)	1 (7.1%)
3	1 (5.0%)	0
>=4	2 (10.0%)	1 (7.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	4 (11.4%)	5 (15.2%)
Censored	31 (88.6%)	28 (84.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (11.0, NE)	NE (1.4, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	94.3% (79.0%, 98.5%)	86.3% (67.5%, 94.6%)
Month 12	90.7% (73.5%, 96.9%)	82.2% (62.2%, 92.2%)
Month 18	90.7% (73.5%, 96.9%)	82.2% (62.2%, 92.2%)
Month 24	90.7% (73.5%, 96.9%)	82.2% (62.2%, 92.2%)
Month 30	86.1% (66.4%, 94.7%)	82.2% (62.2%, 92.2%)
Month 36	86.1% (66.4%, 94.7%)	82.2% (62.2%, 92.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.65 (0.441, 6.136)	
p-value of 2-sided stratified log-rank test	0.4532	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	4	5
0	3 (75.0%)	3 (60.0%)
1	1 (25.0%)	1 (20.0%)
2	0	1 (20.0%)
3	0	0
>=4	0	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	9 (13.4%)	7 (10.9%)
Censored	58 (86.6%)	57 (89.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (5.6, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	86.3% (74.4%, 92.9%)	90.0% (79.1%, 95.4%)
Month 12	86.3% (74.4%, 92.9%)	88.0% (76.3%, 94.1%)
Month 18	83.2% (69.6%, 91.1%)	88.0% (76.3%, 94.1%)
Month 24	83.2% (69.6%, 91.1%)	88.0% (76.3%, 94.1%)
Month 30	83.2% (69.6%, 91.1%)	88.0% (76.3%, 94.1%)
Month 36	83.2% (69.6%, 91.1%)	88.0% (76.3%, 94.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.74 (0.277, 1.999)	
p-value of 2-sided stratified log-rank test	0.5583	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	9	7
0	5 (55.6%)	2 (28.6%)
1	0	0
2	1 (11.1%)	2 (28.6%)
3	1 (11.1%)	0
>=4	2 (22.2%)	3 (42.9%)
p-value from Interaction Test[c]	0.6681	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	65 (72.2%)	61 (70.1%)
Censored	25 (27.8%)	26 (29.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.1 (0.8, 1.5)	1.4 (0.8, 1.4)
50%	2.6 (1.6, 5.5)	3.1 (1.8, 4.6)
75%	13.1 (5.8, NE)	16.7 (7.2, NE)
Survival probability (95% CI) at		
Month 6	34.9% (24.8%, 45.2%)	37.0% (26.6%, 47.4%)
Month 12	27.0% (17.6%, 37.4%)	28.3% (18.3%, 39.0%)
Month 18	23.7% (14.6%, 34.0%)	23.6% (13.9%, 34.7%)
Month 24	18.9% (10.3%, 29.6%)	20.6% (11.1%, 32.1%)
Month 30	16.2% (8.0%, 27.1%)	20.6% (11.1%, 32.1%)
Month 36	16.2% (8.0%, 27.1%)	20.6% (11.1%, 32.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.05 (0.738, 1.492)	
p-value of 2-sided stratified log-rank test	0.7885	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	65	61
0	35 (53.8%)	29 (47.5%)
1	8 (12.3%)	10 (16.4%)
2	6 (9.2%)	7 (11.5%)
3	3 (4.6%)	4 (6.6%)
>=4	13 (20.0%)	11 (18.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	31 (88.6%)	26 (78.8%)
Censored	4 (11.4%)	7 (21.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 1.3)	0.7 (0.7, 0.8)
50%	1.4 (1.0, 2.8)	1.4 (0.8, 1.6)
75%	10.3 (2.2, 19.8)	2.1 (1.4, 17.4)
Survival probability (95% CI) at		
Month 6	28.6% (14.9%, 43.8%)	16.3% (5.5%, 32.2%)
Month 12	22.5% (10.4%, 37.4%)	12.2% (3.3%, 27.5%)
Month 18	12.9% (4.2%, 26.5%)	8.1% (1.5%, 22.5%)
Month 24	9.6% (2.5%, 22.6%)	8.1% (1.5%, 22.5%)
Month 30	9.6% (2.5%, 22.6%)	8.1% (1.5%, 22.5%)
Month 36	9.6% (2.5%, 22.6%)	8.1% (1.5%, 22.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.79 (0.461, 1.349)	
p-value of 2-sided stratified log-rank test	0.4163	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	31	26
0	11 (35.5%)	10 (38.5%)
1	10 (32.3%)	4 (15.4%)
2	1 (3.2%)	1 (3.8%)
3	4 (12.9%)	3 (11.5%)
>=4	5 (16.1%)	8 (30.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	50 (74.6%)	50 (78.1%)
Censored	17 (25.4%)	14 (21.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 1.5)	0.9 (0.7, 1.5)
50%	2.3 (1.5, 3.5)	2.1 (1.5, 2.8)
75%	9.3 (3.5, 11.6)	5.6 (2.8, 20.7)
Survival probability (95% CI) at		
Month 6	28.9% (17.7%, 41.1%)	24.7% (14.7%, 36.0%)
Month 12	11.8% (4.1%, 23.8%)	22.6% (13.0%, 33.9%)
Month 18	NE (NE, NE)	19.8% (10.4%, 31.4%)
Month 24	NE (NE, NE)	10.6% (2.7%, 24.6%)
Month 30	NE (NE, NE)	10.6% (2.7%, 24.6%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.04 (0.698, 1.561)	
p-value of 2-sided stratified log-rank test	0.8273	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	50	50
0	25 (50.0%)	25 (50.0%)
1	8 (16.0%)	8 (16.0%)
2	5 (10.0%)	7 (14.0%)
3	5 (10.0%)	2 (4.0%)
>=4	7 (14.0%)	8 (16.0%)
p-value from Interaction Test[c]	0.4338	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	78 (86.7%)	76 (87.4%)
Censored	12 (13.3%)	11 (12.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.2 (0.8, 1.5)	1.4 (0.8, 1.4)
50%	2.6 (1.7, 4.9)	3.4 (1.8, 4.6)
75%	11.8 (6.0, 20.8)	10.8 (7.2, 18.2)
Survival probability (95% CI) at		
Month 6	33.9% (24.2%, 43.9%)	36.6% (26.5%, 46.7%)
Month 12	23.9% (15.4%, 33.4%)	24.5% (15.8%, 34.3%)
Month 18	19.9% (12.1%, 29.2%)	16.4% (9.1%, 25.4%)
Month 24	12.8% (6.5%, 21.3%)	9.5% (4.3%, 17.4%)
Month 30	11.2% (5.3%, 19.5%)	8.2% (3.4%, 15.7%)
Month 36	9.3% (4.0%, 17.6%)	8.2% (3.4%, 15.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.01 (0.732, 1.388)	
p-value of 2-sided stratified log-rank test	0.9590	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	78	76
0	48 (61.5%)	44 (57.9%)
1	8 (10.3%)	10 (13.2%)
2	6 (7.7%)	7 (9.2%)
3	3 (3.8%)	4 (5.3%)
>=4	13 (16.7%)	11 (14.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	33 (94.3%)	27 (81.8%)
Censored	2 (5.7%)	6 (18.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 1.3)	0.7 (0.7, 0.8)
50%	1.4 (1.0, 2.8)	1.4 (0.8, 1.6)
75%	10.3 (2.2, 17.0)	2.1 (1.4, 7.0)
Survival probability (95% CI) at		
Month 6	28.6% (14.9%, 43.8%)	14.0% (4.4%, 28.9%)
Month 12	22.9% (10.8%, 37.6%)	10.5% (2.7%, 24.6%)
Month 18	11.4% (3.6%, 24.2%)	7.0% (1.2%, 20.0%)
Month 24	8.6% (2.2%, 20.6%)	7.0% (1.2%, 20.0%)
Month 30	5.7% (1.0%, 16.7%)	7.0% (1.2%, 20.0%)
Month 36	5.7% (1.0%, 16.7%)	7.0% (1.2%, 20.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.80 (0.474, 1.349)	
p-value of 2-sided stratified log-rank test	0.4316	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	33	27
0	13 (39.4%)	11 (40.7%)
1	10 (30.3%)	4 (14.8%)
2	1 (3.0%)	1 (3.7%)
3	4 (12.1%)	3 (11.1%)
>=4	5 (15.2%)	8 (29.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	62 (92.5%)	61 (95.3%)
Censored	5 (7.5%)	3 (4.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 1.4)	0.8 (0.7, 1.4)
50%	2.3 (1.5, 3.0)	2.1 (1.5, 2.8)
75%	5.6 (3.5, 9.7)	6.9 (2.8, 15.0)
Survival probability (95% CI) at		
Month 6	24.1% (14.3%, 35.3%)	25.0% (15.2%, 36.0%)
Month 12	8.6% (3.2%, 17.4%)	20.0% (11.2%, 30.6%)
Month 18	3.4% (0.6%, 10.5%)	11.7% (5.2%, 21.0%)
Month 24	1.7% (0.1%, 8.0%)	5.8% (1.6%, 14.1%)
Month 30	0 (NE, NE)	1.9% (0.2%, 8.9%)
Month 36	0 (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.16 (0.806, 1.675)	
p-value of 2-sided stratified log-rank test	0.4083	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	62	61
0	37 (59.7%)	36 (59.0%)
1	8 (12.9%)	8 (13.1%)
2	5 (8.1%)	7 (11.5%)
3	5 (8.1%)	2 (3.3%)
>=4	7 (11.3%)	8 (13.1%)
p-value from Interaction Test[c]	0.3885	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	36 (40.0%)	30 (34.5%)
Censored	54 (60.0%)	57 (65.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 3.5)	3.5 (1.3, 10.9)
50%	NE (16.1, NE)	NE (21.5, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	63.1% (51.9%, 72.3%)	70.3% (59.3%, 78.9%)
Month 12	61.4% (50.2%, 70.9%)	65.1% (53.3%, 74.6%)
Month 18	57.5% (45.6%, 67.7%)	63.0% (50.8%, 73.0%)
Month 24	55.3% (43.2%, 65.9%)	60.1% (47.2%, 70.9%)
Month 30	55.3% (43.2%, 65.9%)	60.1% (47.2%, 70.9%)
Month 36	55.3% (43.2%, 65.9%)	60.1% (47.2%, 70.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.80 (0.495, 1.306)	
p-value of 2-sided stratified log-rank test	0.3831	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	36	30
0	20 (55.6%)	15 (50.0%)
1	3 (8.3%)	5 (16.7%)
2	2 (5.6%)	4 (13.3%)
3	2 (5.6%)	0
>=4	9 (25.0%)	6 (20.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	8 (22.9%)	2 (6.1%)
Censored	27 (77.1%)	31 (93.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	36.1 (1.8, NE)	NE (4.6, NE)
50%	NE (36.1, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	82.4% (64.9%, 91.7%)	91.7% (70.6%, 97.8%)
Month 12	79.1% (61.0%, 89.5%)	91.7% (70.6%, 97.8%)
Month 18	79.1% (61.0%, 89.5%)	91.7% (70.6%, 97.8%)
Month 24	79.1% (61.0%, 89.5%)	91.7% (70.6%, 97.8%)
Month 30	79.1% (61.0%, 89.5%)	91.7% (70.6%, 97.8%)
Month 36	79.1% (61.0%, 89.5%)	91.7% (70.6%, 97.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.30 (0.064, 1.416)	
p-value of 2-sided stratified log-rank test	0.1067	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	8	2
0	6 (75.0%)	1 (50.0%)
1	1 (12.5%)	0
2	0	1 (50.0%)
3	0	0
>=4	1 (12.5%)	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	13 (19.4%)	8 (12.5%)
Censored	54 (80.6%)	56 (87.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (2.6, NE)	NE (13.8, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	79.8% (67.2%, 88.0%)	90.2% (79.5%, 95.5%)
Month 12	77.4% (64.1%, 86.3%)	87.8% (75.8%, 94.1%)
Month 18	77.4% (64.1%, 86.3%)	84.8% (71.3%, 92.3%)
Month 24	77.4% (64.1%, 86.3%)	84.8% (71.3%, 92.3%)
Month 30	77.4% (64.1%, 86.3%)	84.8% (71.3%, 92.3%)
Month 36	77.4% (64.1%, 86.3%)	84.8% (71.3%, 92.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.58 (0.240, 1.399)	
p-value of 2-sided stratified log-rank test	0.2181	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	13	8
0	6 (46.2%)	4 (50.0%)
1	3 (23.1%)	1 (12.5%)
2	3 (23.1%)	1 (12.5%)
3	1 (7.7%)	0
>=4	0	2 (25.0%)
p-value from Interaction Test[c]	0.3992	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	86 (95.6%)	83 (95.4%)
Censored	4 (4.4%)	4 (4.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (NE, NE)	0.7 (NE, NE)
50%	0.8 (0.7, 0.8)	0.8 (0.7, 0.8)
75%	0.9 (0.8, 0.9)	0.9 (0.8, 1.1)
Survival probability (95% CI) at		
Month 6	2.3% (0.4%, 7.2%)	4.7% (1.5%, 10.6%)
Month 12	2.3% (0.4%, 7.2%)	4.7% (1.5%, 10.6%)
Month 18	2.3% (0.4%, 7.2%)	0 (NE, NE)
Month 24	2.3% (0.4%, 7.2%)	0 (NE, NE)
Month 30	2.3% (0.4%, 7.2%)	0 (NE, NE)
Month 36	NE (NE, NE)	0 (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.09 (0.802, 1.483)	
p-value of 2-sided stratified log-rank test	0.5652	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	86	83
0	11 (12.8%)	18 (21.7%)
1	17 (19.8%)	11 (13.3%)
2	8 (9.3%)	9 (10.8%)
3	7 (8.1%)	3 (3.6%)
>=4	43 (50.0%)	42 (50.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	33 (94.3%)	29 (87.9%)
Censored	2 (5.7%)	4 (12.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (NE, NE)	0.7 (NE, NE)
50%	0.8 (0.7, 0.9)	0.7 (0.7, 0.8)
75%	0.9 (0.8, 1.0)	0.8 (0.8, 0.9)
Survival probability (95% CI) at		
Month 6	5.7% (1.0%, 16.7%)	3.3% (0.2%, 14.5%)
Month 12	5.7% (1.0%, 16.7%)	3.3% (0.2%, 14.5%)
Month 18	5.7% (1.0%, 16.7%)	3.3% (0.2%, 14.5%)
Month 24	5.7% (1.0%, 16.7%)	3.3% (0.2%, 14.5%)
Month 30	5.7% (1.0%, 16.7%)	3.3% (0.2%, 14.5%)
Month 36	5.7% (1.0%, 16.7%)	3.3% (0.2%, 14.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.65 (0.388, 1.103)	
p-value of 2-sided stratified log-rank test	0.1621	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	33	29
0	5 (15.2%)	4 (13.8%)
1	2 (6.1%)	5 (17.2%)
2	3 (9.1%)	2 (6.9%)
3	2 (6.1%)	2 (6.9%)
>=4	21 (63.6%)	16 (55.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	58 (86.6%)	58 (90.6%)
Censored	9 (13.4%)	6 (9.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (NE, NE)	0.7 (NE, NE)
50%	0.8 (0.7, 0.8)	0.8 (0.7, 0.8)
75%	0.9 (0.8, 1.0)	0.9 (0.8, 1.0)
Survival probability (95% CI) at		
Month 6	4.9% (1.3%, 12.4%)	6.5% (2.1%, 14.4%)
Month 12	4.9% (1.3%, 12.4%)	6.5% (2.1%, 14.4%)
Month 18	4.9% (1.3%, 12.4%)	6.5% (2.1%, 14.4%)
Month 24	4.9% (1.3%, 12.4%)	6.5% (2.1%, 14.4%)
Month 30	NE (NE, NE)	NE (NE, NE)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.98 (0.677, 1.419)	
p-value of 2-sided stratified log-rank test	0.8732	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	58	58
0	4 (6.9%)	3 (5.2%)
1	9 (15.5%)	9 (15.5%)
2	7 (12.1%)	6 (10.3%)
3	4 (6.9%)	6 (10.3%)
>=4	34 (58.6%)	34 (58.6%)
p-value from Interaction Test[c]	0.2010	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	88 (97.8%)	85 (97.7%)
Censored	2 (2.2%)	2 (2.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (NE, NE)	0.7 (NE, NE)
50%	0.8 (0.7, 0.8)	0.8 (0.7, 0.8)
75%	0.9 (0.8, 1.0)	0.9 (0.8, 1.1)
Survival probability (95% CI) at		
Month 6	2.2% (0.4%, 7.1%)	4.7% (1.5%, 10.6%)
Month 12	2.2% (0.4%, 7.1%)	3.1% (0.7%, 8.8%)
Month 18	2.2% (0.4%, 7.1%)	0 (NE, NE)
Month 24	2.2% (0.4%, 7.1%)	0 (NE, NE)
Month 30	1.1% (0.1%, 5.5%)	0 (NE, NE)
Month 36	NE (NE, NE)	0 (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.04 (0.765, 1.407)	
p-value of 2-sided stratified log-rank test	0.8100	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	88	85
0	13 (14.8%)	20 (23.5%)
1	17 (19.3%)	11 (12.9%)
2	8 (9.1%)	9 (10.6%)
3	7 (8.0%)	3 (3.5%)
>=4	43 (48.9%)	42 (49.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	33 (94.3%)	29 (87.9%)
Censored	2 (5.7%)	4 (12.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (NE, NE)	0.7 (NE, NE)
50%	0.8 (0.7, 0.9)	0.7 (0.7, 0.8)
75%	0.9 (0.8, 1.0)	0.8 (0.8, 0.9)
Survival probability (95% CI) at		
Month 6	5.7% (1.0%, 16.7%)	3.3% (0.2%, 14.5%)
Month 12	5.7% (1.0%, 16.7%)	3.3% (0.2%, 14.5%)
Month 18	5.7% (1.0%, 16.7%)	3.3% (0.2%, 14.5%)
Month 24	5.7% (1.0%, 16.7%)	3.3% (0.2%, 14.5%)
Month 30	5.7% (1.0%, 16.7%)	3.3% (0.2%, 14.5%)
Month 36	5.7% (1.0%, 16.7%)	3.3% (0.2%, 14.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.65 (0.388, 1.103)	
p-value of 2-sided stratified log-rank test	0.1621	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	33	29
0	5 (15.2%)	4 (13.8%)
1	2 (6.1%)	5 (17.2%)
2	3 (9.1%)	2 (6.9%)
3	2 (6.1%)	2 (6.9%)
>=4	21 (63.6%)	16 (55.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	64 (95.5%)	63 (98.4%)
Censored	3 (4.5%)	1 (1.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (NE, NE)	0.7 (NE, NE)
50%	0.8 (0.7, 0.8)	0.8 (0.7, 0.8)
75%	0.9 (0.9, 1.1)	0.9 (0.8, 1.0)
Survival probability (95% CI) at		
Month 6	4.7% (1.2%, 11.8%)	7.8% (2.9%, 16.0%)
Month 12	3.1% (0.6%, 9.7%)	6.3% (2.0%, 14.0%)
Month 18	1.6% (0.1%, 7.4%)	4.7% (1.2%, 11.8%)
Month 24	1.6% (0.1%, 7.4%)	2.3% (0.2%, 9.6%)
Month 30	0 (NE, NE)	0 (NE, NE)
Month 36	0 (NE, NE)	0 (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.98 (0.686, 1.395)	
p-value of 2-sided stratified log-rank test	0.8988	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	64	63
0	10 (15.6%)	8 (12.7%)
1	9 (14.1%)	9 (14.3%)
2	7 (10.9%)	6 (9.5%)
3	4 (6.3%)	6 (9.5%)
>=4	34 (53.1%)	34 (54.0%)
p-value from Interaction Test[c]	0.2571	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	7 (7.8%)	4 (4.6%)
Censored	83 (92.2%)	83 (95.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (NE, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	95.0% (87.2%, 98.1%)	98.8% (91.8%, 99.8%)
Month 12	90.4% (80.8%, 95.3%)	95.1% (85.3%, 98.4%)
Month 18	90.4% (80.8%, 95.3%)	93.2% (82.5%, 97.4%)
Month 24	90.4% (80.8%, 95.3%)	93.2% (82.5%, 97.4%)
Month 30	90.4% (80.8%, 95.3%)	93.2% (82.5%, 97.4%)
Month 36	90.4% (80.8%, 95.3%)	93.2% (82.5%, 97.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.52 (0.152, 1.783)	
p-value of 2-sided stratified log-rank test	0.2900	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	7	4
0	4 (57.1%)	3 (75.0%)
1	0	0
2	0	0
3	0	0
>=4	3 (42.9%)	1 (25.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	2 (5.7%)	2 (6.1%)
Censored	33 (94.3%)	31 (93.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (NE, NE)	NE (6.3, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	94.1% (78.5%, 98.5%)	100% (100%, 100%)
Month 12	94.1% (78.5%, 98.5%)	91.5% (70.0%, 97.8%)
Month 18	94.1% (78.5%, 98.5%)	91.5% (70.0%, 97.8%)
Month 24	94.1% (78.5%, 98.5%)	91.5% (70.0%, 97.8%)
Month 30	94.1% (78.5%, 98.5%)	91.5% (70.0%, 97.8%)
Month 36	94.1% (78.5%, 98.5%)	91.5% (70.0%, 97.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.27 (0.179, 9.049)	
p-value of 2-sided stratified log-rank test	0.8080	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	2	2
0	2 (100%)	1 (50.0%)
1	0	0
2	0	0
3	0	0
>=4	0	1 (50.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	6 (9.0%)	3 (4.7%)
Censored	61 (91.0%)	61 (95.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (7.7, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	100% (100%, 100%)	98.1% (87.4%, 99.7%)
Month 12	86.2% (71.8%, 93.6%)	95.6% (83.3%, 98.9%)
Month 18	86.2% (71.8%, 93.6%)	92.9% (79.4%, 97.7%)
Month 24	86.2% (71.8%, 93.6%)	92.9% (79.4%, 97.7%)
Month 30	86.2% (71.8%, 93.6%)	92.9% (79.4%, 97.7%)
Month 36	86.2% (71.8%, 93.6%)	92.9% (79.4%, 97.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.42 (0.105, 1.677)	
p-value of 2-sided stratified log-rank test	0.2048	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	6	3
0	1 (16.7%)	2 (66.7%)
1	0	0
2	0	0
3	0	0
>=4	5 (83.3%)	1 (33.3%)
p-value from Interaction Test[c]	0.7718	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	67 (74.4%)	64 (73.6%)
Censored	23 (25.6%)	23 (26.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 1.4)
50%	1.5 (1.1, 2.1)	1.6 (1.4, 2.3)
75%	17.1 (2.8, NE)	13.2 (3.6, NE)
Survival probability (95% CI) at		
Month 6	28.5% (19.4%, 38.3%)	29.1% (19.8%, 39.1%)
Month 12	28.5% (19.4%, 38.3%)	27.0% (17.7%, 37.2%)
Month 18	24.4% (15.4%, 34.5%)	18.6% (9.5%, 30.1%)
Month 24	24.4% (15.4%, 34.5%)	18.6% (9.5%, 30.1%)
Month 30	21.9% (13.0%, 32.4%)	18.6% (9.5%, 30.1%)
Month 36	18.3% (9.2%, 29.8%)	18.6% (9.5%, 30.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.03 (0.728, 1.449)	
p-value of 2-sided stratified log-rank test	0.8702	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	67	64
0	25 (37.3%)	23 (35.9%)
1	8 (11.9%)	15 (23.4%)
2	6 (9.0%)	6 (9.4%)
3	5 (7.5%)	2 (3.1%)
>=4	23 (34.3%)	18 (28.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	23 (65.7%)	23 (69.7%)
Censored	12 (34.3%)	10 (30.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 0.9)
50%	1.4 (0.8, 9.7)	1.4 (0.9, 3.5)
75%	NE (2.1, NE)	31.3 (1.4, NE)
Survival probability (95% CI) at		
Month 6	37.1% (21.6%, 52.7%)	26.7% (12.6%, 43.0%)
Month 12	33.8% (18.8%, 49.4%)	26.7% (12.6%, 43.0%)
Month 18	33.8% (18.8%, 49.4%)	26.7% (12.6%, 43.0%)
Month 24	33.8% (18.8%, 49.4%)	26.7% (12.6%, 43.0%)
Month 30	33.8% (18.8%, 49.4%)	26.7% (12.6%, 43.0%)
Month 36	33.8% (18.8%, 49.4%)	22.9% (9.9%, 39.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.84 (0.467, 1.507)	
p-value of 2-sided stratified log-rank test	0.5500	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	23	23
0	8 (34.8%)	7 (30.4%)
1	2 (8.7%)	2 (8.7%)
2	4 (17.4%)	4 (17.4%)
3	3 (13.0%)	2 (8.7%)
>=4	6 (26.1%)	8 (34.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	48 (71.6%)	42 (65.6%)
Censored	19 (28.4%)	22 (34.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 1.0)
50%	1.2 (0.9, 1.5)	1.6 (1.0, 3.5)
75%	3.0 (1.5, NE)	NE (3.5, NE)
Survival probability (95% CI) at		
Month 6	20.8% (11.6%, 31.8%)	34.2% (22.6%, 46.2%)
Month 12	20.8% (11.6%, 31.8%)	32.2% (20.8%, 44.2%)
Month 18	20.8% (11.6%, 31.8%)	29.7% (18.4%, 41.9%)
Month 24	20.8% (11.6%, 31.8%)	29.7% (18.4%, 41.9%)
Month 30	20.8% (11.6%, 31.8%)	29.7% (18.4%, 41.9%)
Month 36	20.8% (11.6%, 31.8%)	29.7% (18.4%, 41.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.40 (0.918, 2.123)	
p-value of 2-sided stratified log-rank test	0.1126	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	48	42
0	16 (33.3%)	14 (33.3%)
1	3 (6.3%)	8 (19.0%)
2	5 (10.4%)	4 (9.5%)
3	6 (12.5%)	3 (7.1%)
>=4	18 (37.5%)	13 (31.0%)
p-value from Interaction Test[c]	0.3658	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	79 (87.8%)	77 (88.5%)
Censored	11 (12.2%)	10 (11.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 1.4)
50%	1.5 (1.1, 2.2)	1.6 (1.4, 2.3)
75%	12.4 (2.8, 20.1)	12.0 (3.7, 16.7)
Survival probability (95% CI) at		
Month 6	28.7% (19.7%, 38.3%)	30.2% (20.9%, 40.0%)
Month 12	25.1% (16.6%, 34.5%)	24.9% (16.3%, 34.6%)
Month 18	19.9% (12.1%, 29.0%)	11.2% (5.4%, 19.4%)
Month 24	15.9% (9.0%, 24.6%)	6.5% (2.3%, 13.9%)
Month 30	11.9% (6.0%, 20.1%)	6.5% (2.3%, 13.9%)
Month 36	8.7% (3.6%, 16.5%)	6.5% (2.3%, 13.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.95 (0.689, 1.298)	
p-value of 2-sided stratified log-rank test	0.7308	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	79	77
0	37 (46.8%)	36 (46.8%)
1	8 (10.1%)	15 (19.5%)
2	6 (7.6%)	6 (7.8%)
3	5 (6.3%)	2 (2.6%)
>=4	23 (29.1%)	18 (23.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	25 (71.4%)	25 (75.8%)
Censored	10 (28.6%)	8 (24.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 0.9)
50%	1.4 (0.8, 9.7)	1.4 (0.9, 3.5)
75%	37.6 (2.1, NE)	31.3 (1.4, NE)
Survival probability (95% CI) at		
Month 6	37.1% (21.6%, 52.7%)	26.7% (12.6%, 43.0%)
Month 12	34.0% (19.1%, 49.6%)	26.7% (12.6%, 43.0%)
Month 18	30.6% (16.3%, 46.3%)	26.7% (12.6%, 43.0%)
Month 24	30.6% (16.3%, 46.3%)	26.7% (12.6%, 43.0%)
Month 30	30.6% (16.3%, 46.3%)	26.7% (12.6%, 43.0%)
Month 36	30.6% (16.3%, 46.3%)	20.0% (8.1%, 35.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.82 (0.467, 1.438)	
p-value of 2-sided stratified log-rank test	0.4794	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	25	25
0	10 (40.0%)	9 (36.0%)
1	2 (8.0%)	2 (8.0%)
2	4 (16.0%)	4 (16.0%)
3	3 (12.0%)	2 (8.0%)
>=4	6 (24.0%)	8 (32.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	59 (88.1%)	54 (84.4%)
Censored	8 (11.9%)	10 (15.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 0.9)
50%	1.2 (0.9, 1.5)	1.6 (1.0, 3.5)
75%	2.9 (1.5, 8.4)	12.5 (4.0, 32.9)
Survival probability (95% CI) at		
Month 6	17.2% (9.2%, 27.3%)	32.8% (21.7%, 44.3%)
Month 12	13.9% (6.8%, 23.5%)	27.9% (17.5%, 39.2%)
Month 18	10.1% (4.1%, 19.3%)	19.7% (10.9%, 30.3%)
Month 24	10.1% (4.1%, 19.3%)	17.5% (9.1%, 28.1%)
Month 30	8.1% (2.8%, 17.0%)	14.6% (6.7%, 25.5%)
Month 36	8.1% (2.8%, 17.0%)	10.9% (3.8%, 22.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.45 (0.997, 2.114)	
p-value of 2-sided stratified log-rank test	0.0474	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	59	54
0	27 (45.8%)	26 (48.1%)
1	3 (5.1%)	8 (14.8%)
2	5 (8.5%)	4 (7.4%)
3	6 (10.2%)	3 (5.6%)
>=4	18 (30.5%)	13 (24.1%)
p-value from Interaction Test[c]	0.2157	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	10 (11.1%)	12 (13.8%)
Censored	80 (88.9%)	75 (86.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (28.7, NE)	NE (9.8, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	91.6% (83.2%, 95.9%)	87.7% (78.3%, 93.2%)
Month 12	90.0% (80.8%, 94.9%)	84.5% (74.1%, 90.9%)
Month 18	90.0% (80.8%, 94.9%)	84.5% (74.1%, 90.9%)
Month 24	87.8% (77.4%, 93.6%)	84.5% (74.1%, 90.9%)
Month 30	85.1% (73.0%, 92.0%)	84.5% (74.1%, 90.9%)
Month 36	85.1% (73.0%, 92.0%)	84.5% (74.1%, 90.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.31 (0.567, 3.041)	
p-value of 2-sided stratified log-rank test	0.5260	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	10	12
0	5 (50.0%)	4 (33.3%)
1	4 (40.0%)	3 (25.0%)
2	0	3 (25.0%)
3	0	0
>=4	1 (10.0%)	2 (16.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	6 (17.1%)	3 (9.1%)
Censored	29 (82.9%)	30 (90.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (2.8, NE)	NE (4.1, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	85.2% (67.9%, 93.6%)	89.1% (69.6%, 96.4%)
Month 12	82.0% (64.2%, 91.5%)	89.1% (69.6%, 96.4%)
Month 18	82.0% (64.2%, 91.5%)	89.1% (69.6%, 96.4%)
Month 24	82.0% (64.2%, 91.5%)	89.1% (69.6%, 96.4%)
Month 30	82.0% (64.2%, 91.5%)	89.1% (69.6%, 96.4%)
Month 36	82.0% (64.2%, 91.5%)	89.1% (69.6%, 96.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.63 (0.158, 2.523)	
p-value of 2-sided stratified log-rank test	0.5089	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	6	3
0	4 (66.7%)	2 (66.7%)
1	1 (16.7%)	0
2	0	0
3	0	1 (33.3%)
>=4	1 (16.7%)	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	7 (10.4%)	5 (7.8%)
Censored	60 (89.6%)	59 (92.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (18.0, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	91.7% (81.1%, 96.4%)	91.6% (81.0%, 96.4%)
Month 12	89.2% (77.2%, 95.1%)	91.6% (81.0%, 96.4%)
Month 18	89.2% (77.2%, 95.1%)	91.6% (81.0%, 96.4%)
Month 24	85.8% (71.3%, 93.2%)	91.6% (81.0%, 96.4%)
Month 30	85.8% (71.3%, 93.2%)	91.6% (81.0%, 96.4%)
Month 36	85.8% (71.3%, 93.2%)	91.6% (81.0%, 96.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.69 (0.219, 2.176)	
p-value of 2-sided stratified log-rank test	0.5246	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	7	5
0	4 (57.1%)	1 (20.0%)
1	0	0
2	1 (14.3%)	3 (60.0%)
3	0	0
>=4	2 (28.6%)	1 (20.0%)
p-value from Interaction Test[c]	0.5125	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	99 (73.3%)	94 (68.6%)
Censored	36 (26.7%)	43 (31.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (1.4, 1.5)	1.4 (0.9, 2.1)
50%	2.8 (2.1, 3.6)	4.2 (3.0, 8.3)
75%	13.2 (6.2, 39.6)	20.8 (13.8, 34.1)
Survival probability (95% CI) at		
Month 6	33.6% (25.5%, 41.9%)	44.4% (35.6%, 52.9%)
Month 12	25.1% (17.5%, 33.4%)	37.8% (29.2%, 46.4%)
Month 18	22.3% (14.9%, 30.7%)	30.0% (21.7%, 38.7%)
Month 24	20.6% (13.2%, 29.2%)	23.1% (15.2%, 32.0%)
Month 30	17.2% (10.1%, 25.9%)	21.7% (13.9%, 30.6%)
Month 36	17.2% (10.1%, 25.9%)	15.4% (8.1%, 25.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.22 (0.914, 1.634)	
p-value of 2-sided stratified log-rank test	0.1787	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	99	94
0	56 (56.6%)	57 (60.6%)
1	15 (15.2%)	13 (13.8%)
2	8 (8.1%)	5 (5.3%)
3	5 (5.1%)	5 (5.3%)
>=4	15 (15.2%)	14 (14.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	36 (63.2%)	36 (76.6%)
Censored	21 (36.8%)	11 (23.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 2.1)	1.4 (0.8, 1.5)
50%	3.0 (2.1, 4.4)	2.4 (1.4, 4.2)
75%	9.1 (4.4, NE)	8.0 (3.7, NE)
Survival probability (95% CI) at		
Month 6	31.5% (18.9%, 44.8%)	27.9% (15.6%, 41.6%)
Month 12	24.5% (12.5%, 38.5%)	20.3% (9.8%, 33.4%)
Month 18	24.5% (12.5%, 38.5%)	20.3% (9.8%, 33.4%)
Month 24	24.5% (12.5%, 38.5%)	15.2% (5.4%, 29.7%)
Month 30	24.5% (12.5%, 38.5%)	15.2% (5.4%, 29.7%)
Month 36	24.5% (12.5%, 38.5%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.89 (0.543, 1.456)	
p-value of 2-sided stratified log-rank test	0.6380	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	36	36
0	13 (36.1%)	16 (44.4%)
1	5 (13.9%)	4 (11.1%)
2	4 (11.1%)	4 (11.1%)
3	3 (8.3%)	2 (5.6%)
>=4	11 (30.6%)	10 (27.8%)
p-value from Interaction Test[c]	0.1374	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	110 (81.5%)	124 (90.5%)
Censored	25 (18.5%)	13 (9.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (1.2, 1.5)	1.4 (0.9, 2.1)
50%	2.8 (2.1, 3.5)	4.2 (3.0, 6.5)
75%	9.3 (6.2, 19.5)	15.5 (12.0, 20.3)
Survival probability (95% CI) at		
Month 6	33.0% (25.1%, 41.1%)	42.2% (33.8%, 50.4%)
Month 12	22.3% (15.4%, 30.0%)	32.4% (24.6%, 40.4%)
Month 18	19.0% (12.4%, 26.7%)	20.3% (14.0%, 27.5%)
Month 24	15.4% (9.3%, 23.0%)	13.3% (8.2%, 19.7%)
Month 30	11.9% (6.5%, 19.1%)	10.9% (6.3%, 16.9%)
Month 36	11.9% (6.5%, 19.1%)	7.3% (3.6%, 12.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.08 (0.826, 1.402)	
p-value of 2-sided stratified log-rank test	0.6025	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	110	124
0	67 (60.9%)	87 (70.2%)
1	15 (13.6%)	13 (10.5%)
2	8 (7.3%)	5 (4.0%)
3	5 (4.5%)	5 (4.0%)
>=4	15 (13.6%)	14 (11.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	50 (87.7%)	41 (87.2%)
Censored	7 (12.3%)	6 (12.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.1)	1.4 (0.8, 1.5)
50%	3.0 (2.1, 4.4)	2.4 (1.4, 3.8)
75%	6.8 (4.2, 13.0)	7.0 (3.7, 18.5)
Survival probability (95% CI) at		
Month 6	30.0% (18.4%, 42.4%)	26.7% (14.9%, 40.0%)
Month 12	16.0% (7.6%, 27.1%)	20.0% (9.9%, 32.6%)
Month 18	12.0% (4.9%, 22.4%)	17.8% (8.3%, 30.1%)
Month 24	12.0% (4.9%, 22.4%)	7.8% (2.1%, 18.4%)
Month 30	6.0% (1.6%, 14.8%)	7.8% (2.1%, 18.4%)
Month 36	6.0% (1.6%, 14.8%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.96 (0.617, 1.500)	
p-value of 2-sided stratified log-rank test	0.8653	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	50	41
0	27 (54.0%)	21 (51.2%)
1	5 (10.0%)	4 (9.8%)
2	4 (8.0%)	4 (9.8%)
3	3 (6.0%)	2 (4.9%)
>=4	11 (22.0%)	10 (24.4%)
p-value from Interaction Test[c]	0.5049	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	38 (28.1%)	30 (21.9%)
Censored	97 (71.9%)	107 (78.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.4 (1.1, NE)	NE (1.8, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	72.2% (63.6%, 79.1%)	78.3% (70.1%, 84.5%)
Month 12	72.2% (63.6%, 79.1%)	77.2% (68.9%, 83.6%)
Month 18	69.7% (60.6%, 77.1%)	75.8% (67.1%, 82.6%)
Month 24	69.7% (60.6%, 77.1%)	75.8% (67.1%, 82.6%)
Month 30	69.7% (60.6%, 77.1%)	75.8% (67.1%, 82.6%)
Month 36	69.7% (60.6%, 77.1%)	75.8% (67.1%, 82.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.76 (0.473, 1.236)	
p-value of 2-sided stratified log-rank test	0.2766	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	38	30
0	12 (31.6%)	12 (40.0%)
1	12 (31.6%)	4 (13.3%)
2	3 (7.9%)	3 (10.0%)
3	0	2 (6.7%)
>=4	11 (28.9%)	9 (30.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	16 (28.1%)	10 (21.3%)
Censored	41 (71.9%)	37 (78.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (0.9, NE)	NE (2.1, NE)
50%	NE (23.8, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	74.8% (60.6%, 84.6%)	79.7% (64.5%, 88.9%)
Month 12	74.8% (60.6%, 84.6%)	76.9% (61.2%, 86.9%)
Month 18	74.8% (60.6%, 84.6%)	76.9% (61.2%, 86.9%)
Month 24	63.3% (45.5%, 76.7%)	76.9% (61.2%, 86.9%)
Month 30	63.3% (45.5%, 76.7%)	76.9% (61.2%, 86.9%)
Month 36	NE (NE, NE)	76.9% (61.2%, 86.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Lymphoedema Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.79 (0.355, 1.753)	
p-value of 2-sided stratified log-rank test	0.5617	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	16	10
0	7 (43.8%)	6 (60.0%)
1	5 (31.3%)	1 (10.0%)
2	0	0
3	1 (6.3%)	1 (10.0%)
>=4	3 (18.8%)	2 (20.0%)
p-value from Interaction Test[c]	0.8776	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	71 (52.6%)	74 (54.0%)
Censored	64 (47.4%)	63 (46.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (1.4, 2.1)	1.6 (1.4, 2.1)
50%	10.2 (2.8, 35.4)	12.8 (2.8, 21.8)
75%	NE (NE, NE)	NE (32.3, NE)
Survival probability (95% CI) at		
Month 6	54.4% (45.4%, 62.5%)	53.1% (44.0%, 61.3%)
Month 12	47.8% (38.7%, 56.3%)	50.1% (41.0%, 58.5%)
Month 18	46.7% (37.6%, 55.3%)	45.0% (35.5%, 53.9%)
Month 24	45.2% (36.0%, 54.0%)	40.1% (30.4%, 49.7%)
Month 30	41.9% (32.3%, 51.1%)	36.3% (26.3%, 46.4%)
Month 36	39.5% (29.5%, 49.4%)	33.9% (23.6%, 44.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.90 (0.651, 1.252)	
p-value of 2-sided stratified log-rank test	0.5283	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	71	74
0	42 (59.2%)	47 (63.5%)
1	15 (21.1%)	8 (10.8%)
2	7 (9.9%)	7 (9.5%)
3	2 (2.8%)	3 (4.1%)
>=4	5 (7.0%)	9 (12.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	29 (50.9%)	21 (44.7%)
Censored	28 (49.1%)	26 (55.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (0.8, 2.9)	2.5 (1.0, 8.2)
50%	4.4 (2.9, 14.9)	21.7 (5.6, NE)
75%	NE (14.6, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	45.4% (30.4%, 59.2%)	63.8% (47.8%, 76.1%)
Month 12	41.6% (26.4%, 56.2%)	52.6% (36.3%, 66.6%)
Month 18	33.6% (18.6%, 49.3%)	52.6% (36.3%, 66.6%)
Month 24	33.6% (18.6%, 49.3%)	48.2% (31.3%, 63.3%)
Month 30	33.6% (18.6%, 49.3%)	48.2% (31.3%, 63.3%)
Month 36	33.6% (18.6%, 49.3%)	48.2% (31.3%, 63.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.53 (0.849, 2.758)	
p-value of 2-sided stratified log-rank test	0.1524	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	29	21
0	20 (69.0%)	9 (42.9%)
1	5 (17.2%)	3 (14.3%)
2	0	2 (9.5%)
3	1 (3.4%)	3 (14.3%)
>=4	3 (10.3%)	4 (19.0%)
p-value from Interaction Test[c]	0.1235	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	97 (71.9%)	114 (83.2%)
Censored	38 (28.1%)	23 (16.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (1.0, 2.1)	1.6 (1.4, 2.1)
50%	8.4 (2.8, 16.5)	6.9 (3.5, 12.5)
75%	32.1 (23.2, NE)	21.5 (15.4, 27.7)
Survival probability (95% CI) at		
Month 6	53.7% (44.8%, 61.7%)	51.5% (42.7%, 59.5%)
Month 12	44.4% (35.6%, 52.8%)	42.7% (34.1%, 50.9%)
Month 18	40.7% (32.1%, 49.2%)	30.6% (22.9%, 38.7%)
Month 24	33.2% (24.9%, 41.7%)	21.5% (14.8%, 29.0%)
Month 30	25.6% (18.0%, 33.8%)	16.5% (10.5%, 23.5%)
Month 36	22.1% (14.8%, 30.3%)	12.8% (7.4%, 19.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.77 (0.582, 1.010)	
p-value of 2-sided stratified log-rank test	0.0544	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	97	114
0	68 (70.1%)	87 (76.3%)
1	15 (15.5%)	8 (7.0%)
2	7 (7.2%)	7 (6.1%)
3	2 (2.1%)	3 (2.6%)
>=4	5 (5.2%)	9 (7.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	46 (80.7%)	35 (74.5%)
Censored	11 (19.3%)	12 (25.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 2.2)	2.5 (1.0, 4.9)
50%	4.4 (2.2, 6.1)	9.6 (4.1, 21.7)
75%	12.4 (6.1, 21.1)	32.4 (19.0, NE)
Survival probability (95% CI) at		
Month 6	38.7% (25.7%, 51.5%)	60.0% (44.3%, 72.6%)
Month 12	25.1% (14.4%, 37.4%)	46.2% (31.2%, 60.0%)
Month 18	17.4% (8.6%, 28.8%)	41.6% (27.1%, 55.5%)
Month 24	13.5% (6.0%, 24.2%)	31.9% (18.8%, 45.9%)
Month 30	13.5% (6.0%, 24.2%)	29.5% (16.8%, 43.3%)
Month 36	13.5% (6.0%, 24.2%)	23.2% (11.5%, 37.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.61 (1.010, 2.563)	
p-value of 2-sided stratified log-rank test	0.0376	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	46	35
0	37 (80.4%)	23 (65.7%)
1	5 (10.9%)	3 (8.6%)
2	0	2 (5.7%)
3	1 (2.2%)	3 (8.6%)
>=4	3 (6.5%)	4 (11.4%)
p-value from Interaction Test[c]	0.0096	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	53 (39.3%)	43 (31.4%)
Censored	82 (60.7%)	94 (68.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.7 (1.6, 4.1)	3.6 (1.4, 10.9)
50%	NE (11.3, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	64.9% (56.0%, 72.5%)	72.8% (64.2%, 79.7%)
Month 12	58.9% (49.5%, 67.1%)	66.5% (57.2%, 74.3%)
Month 18	57.6% (48.1%, 66.0%)	65.4% (55.9%, 73.3%)
Month 24	56.2% (46.6%, 64.8%)	63.8% (54.0%, 72.0%)
Month 30	56.2% (46.6%, 64.8%)	63.8% (54.0%, 72.0%)
Month 36	56.2% (46.6%, 64.8%)	63.8% (54.0%, 72.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.82 (0.548, 1.230)	
p-value of 2-sided stratified log-rank test	0.3292	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	53	43
0	33 (62.3%)	22 (51.2%)
1	6 (11.3%)	3 (7.0%)
2	3 (5.7%)	8 (18.6%)
3	5 (9.4%)	1 (2.3%)
>=4	6 (11.3%)	9 (20.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	23 (40.4%)	21 (44.7%)
Censored	34 (59.6%)	26 (55.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.9, 5.7)	1.4 (0.8, 3.0)
50%	23.8 (5.7, NE)	NE (3.0, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	62.3% (47.3%, 74.2%)	55.6% (40.0%, 68.6%)
Month 12	53.5% (37.7%, 67.0%)	52.3% (36.4%, 65.9%)
Month 18	53.5% (37.7%, 67.0%)	52.3% (36.4%, 65.9%)
Month 24	49.0% (32.4%, 63.7%)	52.3% (36.4%, 65.9%)
Month 30	49.0% (32.4%, 63.7%)	52.3% (36.4%, 65.9%)
Month 36	NE (NE, NE)	52.3% (36.4%, 65.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Urological Symptoms Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.18 (0.644, 2.176)	
p-value of 2-sided stratified log-rank test	0.5896	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	23	21
0	10 (43.5%)	11 (52.4%)
1	3 (13.0%)	1 (4.8%)
2	1 (4.3%)	3 (14.3%)
3	3 (13.0%)	0
>=4	6 (26.1%)	6 (28.6%)
p-value from Interaction Test[c]	0.2666	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	72 (53.3%)	63 (46.0%)
Censored	63 (46.7%)	74 (54.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.4, 3.5)	2.1 (1.4, 3.8)
50%	18.8 (7.3, 31.1)	26.2 (9.7, 38.2)
75%	NE (33.7, NE)	NE (38.2, NE)
Survival probability (95% CI) at		
Month 6	61.2% (52.2%, 69.0%)	65.6% (56.6%, 73.1%)
Month 12	50.8% (41.5%, 59.4%)	57.6% (48.2%, 66.0%)
Month 18	50.8% (41.5%, 59.4%)	52.6% (42.7%, 61.5%)
Month 24	45.1% (35.4%, 54.4%)	52.6% (42.7%, 61.5%)
Month 30	41.9% (32.0%, 51.5%)	45.7% (35.1%, 55.6%)
Month 36	34.7% (24.5%, 45.0%)	40.5% (29.1%, 51.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.13 (0.806, 1.599)	
p-value of 2-sided stratified log-rank test	0.4681	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	72	63
0	50 (69.4%)	44 (69.8%)
1	13 (18.1%)	11 (17.5%)
2	3 (4.2%)	5 (7.9%)
3	3 (4.2%)	3 (4.8%)
>=4	3 (4.2%)	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	27 (47.4%)	28 (59.6%)
Censored	30 (52.6%)	19 (40.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (0.9, 3.9)	2.1 (0.8, 3.1)
50%	12.1 (3.9, NE)	5.6 (2.9, 16.4)
75%	NE (20.8, NE)	NE (9.7, NE)
Survival probability (95% CI) at		
Month 6	60.4% (45.3%, 72.5%)	48.7% (33.5%, 62.3%)
Month 12	50.9% (35.0%, 64.8%)	37.7% (23.2%, 52.1%)
Month 18	43.9% (27.8%, 58.9%)	34.3% (20.0%, 49.0%)
Month 24	35.9% (20.2%, 51.9%)	34.3% (20.0%, 49.0%)
Month 30	35.9% (20.2%, 51.9%)	34.3% (20.0%, 49.0%)
Month 36	35.9% (20.2%, 51.9%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.84 (0.486, 1.456)	
p-value of 2-sided stratified log-rank test	0.5402	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	27	28
0	14 (51.9%)	20 (71.4%)
1	8 (29.6%)	1 (3.6%)
2	2 (7.4%)	0
3	0	2 (7.1%)
>=4	3 (11.1%)	5 (17.9%)
p-value from Interaction Test[c]	0.3603	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	97 (71.9%)	107 (78.1%)
Censored	38 (28.1%)	30 (21.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.4, 3.5)	2.1 (1.4, 3.5)
50%	9.9 (7.3, 18.8)	11.2 (7.9, 14.3)
75%	31.1 (24.6, NE)	27.2 (21.5, 37.4)
Survival probability (95% CI) at		
Month 6	61.1% (52.2%, 68.8%)	62.7% (53.9%, 70.3%)
Month 12	46.2% (37.3%, 54.6%)	48.4% (39.6%, 56.7%)
Month 18	41.7% (32.9%, 50.2%)	36.5% (28.3%, 44.8%)
Month 24	33.8% (25.3%, 42.4%)	29.1% (21.4%, 37.1%)
Month 30	26.8% (19.0%, 35.3%)	22.4% (15.6%, 30.1%)
Month 36	20.3% (13.2%, 28.5%)	19.1% (12.6%, 26.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.97 (0.731, 1.275)	
p-value of 2-sided stratified log-rank test	0.7992	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	97	107
0	75 (77.3%)	88 (82.2%)
1	13 (13.4%)	11 (10.3%)
2	3 (3.1%)	5 (4.7%)
3	3 (3.1%)	3 (2.8%)
>=4	3 (3.1%)	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	47 (82.5%)	40 (85.1%)
Censored	10 (17.5%)	7 (14.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.9, 2.2)	2.1 (0.8, 3.1)
50%	6.1 (2.2, 11.3)	5.6 (2.9, 10.3)
75%	15.3 (11.3, 28.6)	18.5 (9.7, NE)
Survival probability (95% CI) at		
Month 6	50.4% (36.4%, 62.8%)	48.9% (33.7%, 62.4%)
Month 12	36.8% (24.1%, 49.6%)	35.6% (22.0%, 49.3%)
Month 18	23.3% (12.9%, 35.3%)	28.9% (16.6%, 42.4%)
Month 24	19.4% (10.0%, 31.0%)	21.8% (11.1%, 34.8%)
Month 30	11.6% (4.7%, 21.9%)	21.8% (11.1%, 34.8%)
Month 36	11.6% (4.7%, 21.9%)	12.7% (4.5%, 25.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.07 (0.683, 1.661)	
p-value of 2-sided stratified log-rank test	0.7438	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	47	40
0	34 (72.3%)	32 (80.0%)
1	8 (17.0%)	1 (2.5%)
2	2 (4.3%)	0
3	0	2 (5.0%)
>=4	3 (6.4%)	5 (12.5%)
p-value from Interaction Test[c]	0.8848	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	53 (39.3%)	48 (35.0%)
Censored	82 (60.7%)	89 (65.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (1.0, 3.4)	2.8 (1.4, 7.2)
50%	NE (22.5, NE)	NE (22.6, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	63.4% (54.4%, 71.1%)	69.0% (60.2%, 76.2%)
Month 12	60.7% (51.5%, 68.6%)	64.0% (54.7%, 71.8%)
Month 18	59.5% (50.2%, 67.6%)	62.7% (53.2%, 70.7%)
Month 24	58.0% (48.5%, 66.3%)	59.6% (49.6%, 68.2%)
Month 30	58.0% (48.5%, 66.3%)	59.6% (49.6%, 68.2%)
Month 36	56.0% (46.1%, 64.9%)	59.6% (49.6%, 68.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.90 (0.607, 1.332)	
p-value of 2-sided stratified log-rank test	0.5978	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	53	48
0	18 (34.0%)	21 (43.8%)
1	9 (17.0%)	9 (18.8%)
2	3 (5.7%)	5 (10.4%)
3	3 (5.7%)	2 (4.2%)
>=4	20 (37.7%)	11 (22.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	23 (40.4%)	16 (34.0%)
Censored	34 (59.6%)	31 (66.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (0.8, 3.0)	2.2 (1.2, NE)
50%	NE (3.0, NE)	NE (7.6, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	60.9% (46.1%, 72.8%)	66.3% (50.4%, 78.2%)
Month 12	54.9% (39.4%, 68.0%)	63.7% (47.6%, 76.0%)
Month 18	51.0% (34.8%, 65.0%)	63.7% (47.6%, 76.0%)
Month 24	51.0% (34.8%, 65.0%)	63.7% (47.6%, 76.0%)
Month 30	51.0% (34.8%, 65.0%)	63.7% (47.6%, 76.0%)
Month 36	NE (NE, NE)	63.7% (47.6%, 76.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Gastrointestinal Symptoms Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.76 (0.388, 1.494)	
p-value of 2-sided stratified log-rank test	0.4385	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	23	16
0	10 (43.5%)	7 (43.8%)
1	2 (8.7%)	6 (37.5%)
2	2 (8.7%)	1 (6.3%)
3	1 (4.3%)	0
>=4	8 (34.8%)	2 (12.5%)
p-value from Interaction Test[c]	0.5714	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	107 (79.3%)	90 (65.7%)
Censored	28 (20.7%)	47 (34.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.8)	0.7 (0.7, 0.8)
50%	1.1 (0.9, 1.4)	1.5 (1.3, 2.3)
75%	4.4 (2.9, 25.3)	NE (18.0, NE)
Survival probability (95% CI) at		
Month 6	24.0% (17.1%, 31.7%)	35.5% (27.4%, 43.8%)
Month 12	21.1% (14.4%, 28.7%)	34.6% (26.4%, 42.8%)
Month 18	19.9% (13.3%, 27.5%)	32.1% (24.0%, 40.5%)
Month 24	17.4% (11.1%, 25.0%)	30.7% (22.5%, 39.2%)
Month 30	14.3% (8.2%, 22.1%)	29.2% (21.0%, 37.9%)
Month 36	14.3% (8.2%, 22.1%)	27.1% (18.7%, 36.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.33 (1.000, 1.768)	
p-value of 2-sided stratified log-rank test	0.0435	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	107	90
0	49 (45.8%)	34 (37.8%)
1	11 (10.3%)	12 (13.3%)
2	4 (3.7%)	9 (10.0%)
3	4 (3.7%)	6 (6.7%)
>=4	39 (36.4%)	29 (32.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	35 (61.4%)	29 (61.7%)
Censored	22 (38.6%)	18 (38.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.8, 1.2)
50%	1.8 (0.9, 2.9)	2.1 (1.0, 16.8)
75%	NE (2.9, NE)	NE (12.9, NE)
Survival probability (95% CI) at		
Month 6	34.2% (21.2%, 47.5%)	44.3% (29.6%, 58.1%)
Month 12	31.5% (18.9%, 45.0%)	40.6% (25.7%, 55.0%)
Month 18	28.4% (16.0%, 42.1%)	33.3% (18.7%, 48.5%)
Month 24	28.4% (16.0%, 42.1%)	29.1% (15.0%, 44.8%)
Month 30	28.4% (16.0%, 42.1%)	29.1% (15.0%, 44.8%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.02 (0.613, 1.681)	
p-value of 2-sided stratified log-rank test	0.9571	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	35	29
0	13 (37.1%)	12 (41.4%)
1	8 (22.9%)	1 (3.4%)
2	3 (8.6%)	3 (10.3%)
3	2 (5.7%)	1 (3.4%)
>=4	9 (25.7%)	12 (41.4%)
p-value from Interaction Test[c]	0.5140	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	120 (88.9%)	115 (83.9%)
Censored	15 (11.1%)	22 (16.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.8)	0.7 (0.7, 0.8)
50%	1.1 (0.9, 1.4)	1.5 (1.3, 2.3)
75%	4.4 (2.9, 14.8)	17.1 (8.8, 25.2)
Survival probability (95% CI) at		
Month 6	24.0% (17.1%, 31.6%)	33.8% (25.9%, 41.8%)
Month 12	18.9% (12.6%, 26.1%)	29.9% (22.4%, 37.8%)
Month 18	17.1% (11.1%, 24.2%)	22.9% (16.2%, 30.4%)
Month 24	12.6% (7.4%, 19.2%)	18.1% (12.0%, 25.1%)
Month 30	7.2% (3.4%, 12.8%)	15.6% (10.0%, 22.4%)
Month 36	7.2% (3.4%, 12.8%)	13.5% (8.2%, 20.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.24 (0.955, 1.609)	
p-value of 2-sided stratified log-rank test	0.1019	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	120	115
0	62 (51.7%)	59 (51.3%)
1	11 (9.2%)	12 (10.4%)
2	4 (3.3%)	9 (7.8%)
3	4 (3.3%)	6 (5.2%)
>=4	39 (32.5%)	29 (25.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	48 (84.2%)	39 (83.0%)
Censored	9 (15.8%)	8 (17.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.1)	0.8 (0.8, 1.2)
50%	2.0 (1.1, 2.9)	2.1 (1.0, 9.8)
75%	6.2 (2.9, 26.5)	16.8 (9.4, NE)
Survival probability (95% CI) at		
Month 6	29.1% (17.7%, 41.4%)	42.2% (27.8%, 56.0%)
Month 12	21.3% (11.5%, 33.1%)	33.3% (20.2%, 47.0%)
Month 18	17.4% (8.7%, 28.7%)	22.2% (11.5%, 35.1%)
Month 24	17.4% (8.7%, 28.7%)	17.5% (8.1%, 29.9%)
Month 30	11.6% (4.8%, 21.8%)	17.5% (8.1%, 29.9%)
Month 36	NE (NE, NE)	14.6% (6.0%, 26.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.03 (0.662, 1.608)	
p-value of 2-sided stratified log-rank test	0.8858	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	48	39
0	26 (54.2%)	22 (56.4%)
1	8 (16.7%)	1 (2.6%)
2	3 (6.3%)	3 (7.7%)
3	2 (4.2%)	1 (2.6%)
>=4	9 (18.8%)	12 (30.8%)
p-value from Interaction Test[c]	0.5202	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	32 (23.7%)	33 (24.1%)
Censored	103 (76.3%)	104 (75.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	21.0 (10.8, NE)	9.2 (4.1, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	84.5% (77.0%, 89.7%)	79.6% (71.5%, 85.7%)
Month 12	82.5% (74.6%, 88.2%)	73.6% (64.7%, 80.7%)
Month 18	78.1% (69.3%, 84.6%)	73.6% (64.7%, 80.7%)
Month 24	72.7% (62.8%, 80.3%)	72.2% (62.9%, 79.5%)
Month 30	71.1% (60.8%, 79.1%)	72.2% (62.9%, 79.5%)
Month 36	69.0% (58.1%, 77.5%)	72.2% (62.9%, 79.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.10 (0.674, 1.792)	
p-value of 2-sided stratified log-rank test	0.7015	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	32	33
0	11 (34.4%)	21 (63.6%)
1	7 (21.9%)	5 (15.2%)
2	6 (18.8%)	2 (6.1%)
3	1 (3.1%)	2 (6.1%)
>=4	7 (21.9%)	3 (9.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	13 (22.8%)	13 (27.7%)
Censored	44 (77.2%)	34 (72.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	13.1 (1.5, NE)	11.1 (1.4, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	77.6% (63.0%, 87.0%)	75.6% (60.2%, 85.6%)
Month 12	77.6% (63.0%, 87.0%)	72.4% (56.3%, 83.4%)
Month 18	70.9% (54.5%, 82.4%)	68.4% (51.0%, 80.7%)
Month 24	70.9% (54.5%, 82.4%)	68.4% (51.0%, 80.7%)
Month 30	70.9% (54.5%, 82.4%)	68.4% (51.0%, 80.7%)
Month 36	70.9% (54.5%, 82.4%)	68.4% (51.0%, 80.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Poor Body Image Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.17 (0.538, 2.556)	
p-value of 2-sided stratified log-rank test	0.6936	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	13	13
0	10 (76.9%)	3 (23.1%)
1	1 (7.7%)	1 (7.7%)
2	0	1 (7.7%)
3	1 (7.7%)	2 (15.4%)
>=4	1 (7.7%)	6 (46.2%)
p-value from Interaction Test[c]	0.8678	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	12 (8.9%)	12 (8.8%)
Censored	123 (91.1%)	125 (91.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (7.0, NE)	NE (5.3, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	86.5% (75.5%, 92.8%)	85.0% (73.1%, 92.0%)
Month 12	80.9% (68.7%, 88.8%)	78.0% (64.0%, 87.1%)
Month 18	80.9% (68.7%, 88.8%)	78.0% (64.0%, 87.1%)
Month 24	80.9% (68.7%, 88.8%)	78.0% (64.0%, 87.1%)
Month 30	80.9% (68.7%, 88.8%)	78.0% (64.0%, 87.1%)
Month 36	80.9% (68.7%, 88.8%)	78.0% (64.0%, 87.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.89 (0.394, 1.995)	
p-value of 2-sided stratified log-rank test	0.7715	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	12	12
0	6 (50.0%)	7 (58.3%)
1	3 (25.0%)	2 (16.7%)
2	2 (16.7%)	1 (8.3%)
3	1 (8.3%)	1 (8.3%)
>=4	0	1 (8.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	5 (8.8%)	1 (2.1%)
Censored	52 (91.2%)	46 (97.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (0.8, NE)	NE (1.0, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	77.7% (54.4%, 90.1%)	95.0% (69.5%, 99.3%)
Month 12	77.7% (54.4%, 90.1%)	95.0% (69.5%, 99.3%)
Month 18	77.7% (54.4%, 90.1%)	95.0% (69.5%, 99.3%)
Month 24	77.7% (54.4%, 90.1%)	95.0% (69.5%, 99.3%)
Month 30	77.7% (54.4%, 90.1%)	95.0% (69.5%, 99.3%)
Month 36	77.7% (54.4%, 90.1%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	4.64 (0.496, 43.425)	
p-value of 2-sided stratified log-rank test	0.1481	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	5	1
0	1 (20.0%)	0
1	3 (60.0%)	1 (100%)
2	0	0
3	0	0
>=4	1 (20.0%)	0
p-value from Interaction Test[c]	0.2469	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	58 (43.0%)	85 (62.0%)
Censored	77 (57.0%)	52 (38.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	11.0 (7.6, 19.2)	9.4 (6.5, 11.8)
50%	26.3 (20.3, 30.7)	16.1 (13.3, 18.7)
75%	37.6 (31.2, NE)	29.3 (22.2, 36.1)
Survival probability (95% CI) at		
Month 6	87.8% (79.4%, 92.9%)	83.7% (75.4%, 89.4%)
Month 12	74.3% (64.1%, 82.0%)	65.4% (55.5%, 73.6%)
Month 18	69.3% (58.7%, 77.8%)	43.4% (33.5%, 52.8%)
Month 24	55.9% (44.5%, 65.8%)	32.2% (23.1%, 41.7%)
Month 30	42.1% (30.7%, 53.0%)	22.9% (14.9%, 31.9%)
Month 36	28.5% (17.8%, 40.1%)	17.4% (10.2%, 26.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.65 (0.464, 0.921)	
p-value of 2-sided stratified log-rank test	0.0144	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	58	85
0	52 (89.7%)	80 (94.1%)
1	3 (5.2%)	2 (2.4%)
2	2 (3.4%)	1 (1.2%)
3	1 (1.7%)	1 (1.2%)
>=4	0	1 (1.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	36 (63.2%)	26 (55.3%)
Censored	21 (36.8%)	21 (44.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	5.3 (1.7, 7.5)	10.3 (4.1, 16.7)
50%	12.4 (6.8, 18.7)	18.5 (12.9, 24.6)
75%	26.3 (14.9, 29.0)	32.4 (20.0, NE)
Survival probability (95% CI) at		
Month 6	70.8% (55.0%, 81.9%)	90.9% (74.4%, 97.0%)
Month 12	51.7% (36.0%, 65.4%)	74.8% (55.8%, 86.6%)
Month 18	36.9% (22.7%, 51.2%)	55.3% (36.4%, 70.6%)
Month 24	32.0% (18.6%, 46.2%)	35.2% (19.1%, 51.9%)
Month 30	11.6% (3.8%, 24.3%)	31.7% (16.3%, 48.3%)
Month 36	11.6% (3.8%, 24.3%)	19.0% (6.9%, 35.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.59 (0.917, 2.767)	
p-value of 2-sided stratified log-rank test	0.0850	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	36	26
0	32 (88.9%)	25 (96.2%)
1	3 (8.3%)	1 (3.8%)
2	0	0
3	0	0
>=4	1 (2.8%)	0
p-value from Interaction Test[c]	0.0102	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	8 (5.9%)	5 (3.6%)
Censored	127 (94.1%)	132 (96.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (13.9, NE)	NE (25.1, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	92.4% (82.7%, 96.8%)	93.6% (83.9%, 97.6%)
Month 12	88.4% (77.0%, 94.4%)	93.6% (83.9%, 97.6%)
Month 18	86.0% (73.5%, 92.9%)	93.6% (83.9%, 97.6%)
Month 24	86.0% (73.5%, 92.9%)	93.6% (83.9%, 97.6%)
Month 30	86.0% (73.5%, 92.9%)	87.8% (67.9%, 95.7%)
Month 36	86.0% (73.5%, 92.9%)	87.8% (67.9%, 95.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.81 (0.264, 2.514)	
p-value of 2-sided stratified log-rank test	0.7174	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	8	5
0	3 (37.5%)	3 (60.0%)
1	1 (12.5%)	1 (20.0%)
2	3 (37.5%)	0
3	0	0
>=4	1 (12.5%)	1 (20.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	3 (5.3%)	2 (4.3%)
Censored	54 (94.7%)	45 (95.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (0.7, NE)	27.7 (2.2, NE)
50%	NE (NE, NE)	NE (27.7, NE)
75%	NE (NE, NE)	NE (27.7, NE)
Survival probability (95% CI) at		
Month 6	90.4% (65.9%, 97.6%)	94.4% (66.6%, 99.2%)
Month 12	83.4% (55.7%, 94.5%)	94.4% (66.6%, 99.2%)
Month 18	83.4% (55.7%, 94.5%)	94.4% (66.6%, 99.2%)
Month 24	83.4% (55.7%, 94.5%)	94.4% (66.6%, 99.2%)
Month 30	83.4% (55.7%, 94.5%)	70.8% (15.9%, 93.7%)
Month 36	83.4% (55.7%, 94.5%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual/Vaginal Problems Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.90 (0.128, 6.420)	
p-value of 2-sided stratified log-rank test	0.9203	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	3	2
0	1 (33.3%)	1 (50.0%)
1	1 (33.3%)	0
2	0	0
3	1 (33.3%)	0
>=4	0	1 (50.0%)
p-value from Interaction Test[c]	0.8222	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	71 (52.6%)	79 (57.7%)
Censored	64 (47.4%)	58 (42.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.4, 4.4)	2.8 (1.4, 4.0)
50%	13.2 (7.4, 37.2)	13.4 (7.0, 22.6)
75%	NE (39.6, NE)	34.1 (27.7, NE)
Survival probability (95% CI) at		
Month 6	62.7% (53.7%, 70.5%)	60.6% (51.5%, 68.6%)
Month 12	52.8% (43.5%, 61.2%)	52.0% (42.6%, 60.5%)
Month 18	47.4% (38.1%, 56.2%)	44.9% (35.4%, 54.0%)
Month 24	42.8% (33.3%, 51.8%)	37.9% (28.2%, 47.5%)
Month 30	41.5% (32.0%, 50.6%)	33.1% (23.5%, 43.1%)
Month 36	41.5% (32.0%, 50.6%)	22.5% (13.2%, 33.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.83 (0.598, 1.145)	
p-value of 2-sided stratified log-rank test	0.2480	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	71	79
0	46 (64.8%)	53 (67.1%)
1	7 (9.9%)	15 (19.0%)
2	4 (5.6%)	2 (2.5%)
3	7 (9.9%)	3 (3.8%)
>=4	7 (9.9%)	6 (7.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	28 (49.1%)	23 (48.9%)
Censored	29 (50.9%)	24 (51.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 3.0)	2.1 (1.2, 8.7)
50%	6.9 (2.3, NE)	14.1 (5.5, NE)
75%	NE (22.5, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	53.6% (38.4%, 66.6%)	64.1% (48.1%, 76.2%)
Month 12	46.9% (31.2%, 61.1%)	58.1% (41.7%, 71.4%)
Month 18	43.3% (27.6%, 58.1%)	42.6% (26.5%, 57.8%)
Month 24	35.0% (19.4%, 51.0%)	42.6% (26.5%, 57.8%)
Month 30	35.0% (19.4%, 51.0%)	42.6% (26.5%, 57.8%)
Month 36	NE (NE, NE)	42.6% (26.5%, 57.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.27 (0.718, 2.254)	
p-value of 2-sided stratified log-rank test	0.4118	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	28	23
0	17 (60.7%)	14 (60.9%)
1	5 (17.9%)	3 (13.0%)
2	2 (7.1%)	2 (8.7%)
3	1 (3.6%)	2 (8.7%)
>=4	3 (10.7%)	2 (8.7%)
p-value from Interaction Test[c]	0.1442	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	99 (73.3%)	115 (83.9%)
Censored	36 (26.7%)	22 (16.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.4, 3.7)	2.8 (1.4, 4.0)
50%	10.1 (6.9, 17.6)	9.8 (6.9, 13.3)
75%	32.1 (21.8, NE)	21.9 (17.3, 29.3)
Survival probability (95% CI) at		
Month 6	61.0% (52.1%, 68.8%)	59.0% (50.2%, 66.8%)
Month 12	47.0% (38.1%, 55.4%)	45.6% (36.9%, 53.9%)
Month 18	40.9% (32.2%, 49.4%)	31.4% (23.6%, 39.5%)
Month 24	32.2% (24.1%, 40.6%)	22.4% (15.6%, 30.0%)
Month 30	28.8% (21.0%, 37.0%)	17.3% (11.3%, 24.5%)
Month 36	22.8% (15.6%, 30.9%)	10.9% (5.9%, 17.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.82 (0.622, 1.074)	
p-value of 2-sided stratified log-rank test	0.1425	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	99	115
0	74 (74.7%)	89 (77.4%)
1	7 (7.1%)	15 (13.0%)
2	4 (4.0%)	2 (1.7%)
3	7 (7.1%)	3 (2.6%)
>=4	7 (7.1%)	6 (5.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	46 (80.7%)	35 (74.5%)
Censored	11 (19.3%)	12 (25.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 2.3)	2.1 (1.2, 5.5)
50%	5.5 (2.3, 6.9)	12.9 (4.5, 17.3)
75%	15.0 (6.9, NE)	32.4 (16.7, NE)
Survival probability (95% CI) at		
Month 6	45.2% (31.7%, 57.8%)	62.2% (46.5%, 74.6%)
Month 12	30.2% (18.6%, 42.6%)	53.3% (37.9%, 66.6%)
Month 18	22.6% (12.6%, 34.5%)	35.2% (21.6%, 49.0%)
Month 24	18.9% (9.7%, 30.3%)	27.8% (15.5%, 41.5%)
Month 30	15.1% (7.1%, 25.9%)	25.3% (13.5%, 38.8%)
Month 36	NE (NE, NE)	21.7% (10.4%, 35.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.47 (0.927, 2.330)	
p-value of 2-sided stratified log-rank test	0.0985	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	46	35
0	35 (76.1%)	26 (74.3%)
1	5 (10.9%)	3 (8.6%)
2	2 (4.3%)	2 (5.7%)
3	1 (2.2%)	2 (5.7%)
>=4	3 (6.5%)	2 (5.7%)
p-value from Interaction Test[c]	0.0188	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	69 (51.1%)	58 (42.3%)
Censored	66 (48.9%)	79 (57.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.4)	1.0 (0.8, 1.4)
50%	3.7 (2.1, NE)	NE (2.4, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	48.2% (39.3%, 56.5%)	56.2% (47.1%, 64.2%)
Month 12	48.2% (39.3%, 56.5%)	55.2% (46.2%, 63.4%)
Month 18	45.8% (36.8%, 54.3%)	55.2% (46.2%, 63.4%)
Month 24	45.8% (36.8%, 54.3%)	55.2% (46.2%, 63.4%)
Month 30	45.8% (36.8%, 54.3%)	55.2% (46.2%, 63.4%)
Month 36	45.8% (36.8%, 54.3%)	55.2% (46.2%, 63.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.83 (0.581, 1.175)	
p-value of 2-sided stratified log-rank test	0.2622	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	69	58
0	21 (30.4%)	17 (29.3%)
1	13 (18.8%)	10 (17.2%)
2	3 (4.3%)	3 (5.2%)
3	9 (13.0%)	7 (12.1%)
>=4	23 (33.3%)	21 (36.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	25 (43.9%)	17 (36.2%)
Censored	32 (56.1%)	30 (63.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.4)	1.4 (0.8, 3.6)
50%	20.2 (2.4, NE)	NE (2.3, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	59.0% (44.2%, 71.1%)	62.1% (46.2%, 74.4%)
Month 12	56.3% (41.3%, 68.8%)	62.1% (46.2%, 74.4%)
Month 18	53.2% (37.9%, 66.3%)	62.1% (46.2%, 74.4%)
Month 24	46.3% (30.5%, 60.7%)	62.1% (46.2%, 74.4%)
Month 30	46.3% (30.5%, 60.7%)	62.1% (46.2%, 74.4%)
Month 36	46.3% (30.5%, 60.7%)	62.1% (46.2%, 74.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Pain in Back and Pelvis Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.69 (0.361, 1.309)	
p-value of 2-sided stratified log-rank test	0.2535	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	25	17
0	7 (28.0%)	4 (23.5%)
1	5 (20.0%)	4 (23.5%)
2	2 (8.0%)	2 (11.8%)
3	3 (12.0%)	1 (5.9%)
>=4	8 (32.0%)	6 (35.3%)
p-value from Interaction Test[c]	0.8099	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	106 (78.5%)	106 (77.4%)
Censored	29 (21.5%)	31 (22.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.4)	0.9 (0.8, 1.4)
50%	1.7 (1.5, 2.1)	1.4 (1.4, 2.1)
75%	3.7 (2.8, NE)	3.9 (2.8, 22.5)
Survival probability (95% CI) at		
Month 6	21.9% (15.2%, 29.4%)	20.5% (14.0%, 27.9%)
Month 12	18.3% (12.1%, 25.6%)	17.9% (11.5%, 25.4%)
Month 18	18.3% (12.1%, 25.6%)	17.9% (11.5%, 25.4%)
Month 24	18.3% (12.1%, 25.6%)	14.3% (7.2%, 23.8%)
Month 30	18.3% (12.1%, 25.6%)	14.3% (7.2%, 23.8%)
Month 36	18.3% (12.1%, 25.6%)	14.3% (7.2%, 23.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.89 (0.675, 1.173)	
p-value of 2-sided stratified log-rank test	0.4285	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	106	106
0	23 (21.7%)	40 (37.7%)
1	3 (2.8%)	5 (4.7%)
2	14 (13.2%)	9 (8.5%)
3	5 (4.7%)	4 (3.8%)
>=4	61 (57.5%)	48 (45.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	45 (78.9%)	39 (83.0%)
Censored	12 (21.1%)	8 (17.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.8)	0.8 (0.7, 0.8)
50%	1.4 (0.8, 1.7)	1.5 (0.8, 2.3)
75%	2.7 (1.6, NE)	3.5 (2.2, 11.1)
Survival probability (95% CI) at		
Month 6	17.0% (8.4%, 28.2%)	17.1% (7.7%, 29.7%)
Month 12	12.7% (4.6%, 25.1%)	11.4% (3.9%, 23.4%)
Month 18	12.7% (4.6%, 25.1%)	11.4% (3.9%, 23.4%)
Month 24	12.7% (4.6%, 25.1%)	11.4% (3.9%, 23.4%)
Month 30	12.7% (4.6%, 25.1%)	11.4% (3.9%, 23.4%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.04 (0.664, 1.643)	
p-value of 2-sided stratified log-rank test	0.8327	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	45	39
0	15 (33.3%)	10 (25.6%)
1	4 (8.9%)	3 (7.7%)
2	3 (6.7%)	2 (5.1%)
3	1 (2.2%)	2 (5.1%)
>=4	22 (48.9%)	22 (56.4%)
p-value from Interaction Test[c]	0.5730	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	122 (90.4%)	127 (92.7%)
Censored	13 (9.6%)	10 (7.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.4)	0.9 (0.8, 1.4)
50%	1.7 (1.5, 2.1)	1.4 (1.4, 2.1)
75%	3.6 (2.8, 11.5)	4.0 (3.2, 8.8)
Survival probability (95% CI) at		
Month 6	21.2% (14.7%, 28.5%)	20.2% (13.9%, 27.3%)
Month 12	17.3% (11.4%, 24.2%)	14.3% (8.9%, 20.9%)
Month 18	14.8% (9.3%, 21.5%)	8.3% (4.3%, 14.0%)
Month 24	13.1% (7.9%, 19.5%)	4.2% (1.5%, 9.2%)
Month 30	7.8% (3.9%, 13.5%)	3.1% (0.9%, 7.8%)
Month 36	7.8% (3.9%, 13.5%)	3.1% (0.9%, 7.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.85 (0.656, 1.105)	
p-value of 2-sided stratified log-rank test	0.2353	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	122	127
0	39 (32.0%)	61 (48.0%)
1	3 (2.5%)	5 (3.9%)
2	14 (11.5%)	9 (7.1%)
3	5 (4.1%)	4 (3.1%)
>=4	61 (50.0%)	48 (37.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	55 (96.5%)	42 (89.4%)
Censored	2 (3.5%)	5 (10.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.9)	0.8 (0.7, 0.8)
50%	1.4 (0.9, 1.7)	1.5 (0.8, 2.3)
75%	2.7 (1.7, 5.3)	3.5 (2.2, 8.0)
Survival probability (95% CI) at		
Month 6	14.3% (6.7%, 24.7%)	17.8% (8.3%, 30.1%)
Month 12	7.1% (2.3%, 15.8%)	11.1% (4.1%, 22.1%)
Month 18	5.4% (1.4%, 13.4%)	11.1% (4.1%, 22.1%)
Month 24	3.6% (0.7%, 10.9%)	8.9% (2.8%, 19.3%)
Month 30	1.8% (0.1%, 8.3%)	8.9% (2.8%, 19.3%)
Month 36	NE (NE, NE)	8.9% (2.8%, 19.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.13 (0.734, 1.730)	
p-value of 2-sided stratified log-rank test	0.5527	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	55	42
0	25 (45.5%)	13 (31.0%)
1	4 (7.3%)	3 (7.1%)
2	3 (5.5%)	2 (4.8%)
3	1 (1.8%)	2 (4.8%)
>=4	22 (40.0%)	22 (52.4%)
p-value from Interaction Test[c]	0.1698	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	27 (20.0%)	19 (13.9%)
Censored	108 (80.0%)	118 (86.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (11.3, NE)	NE (37.3, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	84.5% (77.0%, 89.7%)	85.8% (78.3%, 90.8%)
Month 12	82.4% (74.4%, 88.1%)	85.8% (78.3%, 90.8%)
Month 18	80.1% (71.5%, 86.3%)	85.8% (78.3%, 90.8%)
Month 24	78.7% (69.9%, 85.3%)	85.8% (78.3%, 90.8%)
Month 30	75.7% (66.1%, 83.0%)	85.8% (78.3%, 90.8%)
Month 36	75.7% (66.1%, 83.0%)	85.8% (78.3%, 90.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.73 (0.404, 1.312)	
p-value of 2-sided stratified log-rank test	0.2888	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	27	19
0	13 (48.1%)	10 (52.6%)
1	5 (18.5%)	4 (21.1%)
2	3 (11.1%)	2 (10.5%)
3	2 (7.4%)	0
>=4	4 (14.8%)	3 (15.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	6 (10.5%)	7 (14.9%)
Censored	51 (89.5%)	40 (85.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (23.0, NE)	NE (7.6, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	91.9% (79.7%, 96.9%)	88.9% (75.3%, 95.2%)
Month 12	89.2% (75.9%, 95.4%)	83.6% (68.5%, 91.9%)
Month 18	89.2% (75.9%, 95.4%)	83.6% (68.5%, 91.9%)
Month 24	85.2% (68.8%, 93.4%)	83.6% (68.5%, 91.9%)
Month 30	85.2% (68.8%, 93.4%)	83.6% (68.5%, 91.9%)
Month 36	85.2% (68.8%, 93.4%)	83.6% (68.5%, 91.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Tingling/Numbness Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.27 (0.422, 3.837)	
p-value of 2-sided stratified log-rank test	0.6686	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	6	7
0	6 (100%)	4 (57.1%)
1	0	0
2	0	2 (28.6%)
3	0	0
>=4	0	1 (14.3%)
p-value from Interaction Test[c]	0.3429	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	106 (78.5%)	98 (71.5%)
Censored	29 (21.5%)	39 (28.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	0.9 (0.8, 1.4)
50%	2.6 (2.1, 3.4)	2.1 (1.4, 2.8)
75%	11.6 (5.6, 13.2)	12.3 (5.6, NE)
Survival probability (95% CI) at		
Month 6	32.1% (24.2%, 40.4%)	32.2% (24.2%, 40.4%)
Month 12	22.6% (15.5%, 30.5%)	25.7% (18.1%, 34.0%)
Month 18	16.2% (9.9%, 23.7%)	22.4% (14.8%, 31.1%)
Month 24	12.9% (7.1%, 20.6%)	18.3% (10.7%, 27.5%)
Month 30	11.3% (5.7%, 19.0%)	18.3% (10.7%, 27.5%)
Month 36	11.3% (5.7%, 19.0%)	18.3% (10.7%, 27.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.01 (0.761, 1.340)	
p-value of 2-sided stratified log-rank test	0.9065	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	106	98
0	50 (47.2%)	45 (45.9%)
1	19 (17.9%)	17 (17.3%)
2	10 (9.4%)	9 (9.2%)
3	9 (8.5%)	8 (8.2%)
>=4	18 (17.0%)	19 (19.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	40 (70.2%)	39 (83.0%)
Censored	17 (29.8%)	8 (17.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	0.8 (0.8, 1.5)
50%	1.6 (1.4, 3.5)	2.1 (1.4, 3.1)
75%	11.1 (3.5, NE)	4.6 (2.8, 16.7)
Survival probability (95% CI) at		
Month 6	31.1% (18.6%, 44.5%)	21.0% (10.4%, 34.1%)
Month 12	19.5% (8.3%, 34.1%)	18.0% (8.1%, 31.0%)
Month 18	15.6% (5.6%, 30.1%)	12.0% (4.1%, 24.4%)
Month 24	11.7% (3.3%, 25.8%)	9.0% (2.5%, 20.9%)
Month 30	11.7% (3.3%, 25.8%)	9.0% (2.5%, 20.9%)
Month 36	NE (NE, NE)	9.0% (2.5%, 20.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.84 (0.527, 1.345)	
p-value of 2-sided stratified log-rank test	0.4638	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	40	39
0	21 (52.5%)	19 (48.7%)
1	7 (17.5%)	5 (12.8%)
2	2 (5.0%)	6 (15.4%)
3	3 (7.5%)	1 (2.6%)
>=4	7 (17.5%)	8 (20.5%)
p-value from Interaction Test[c]	0.5967	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	122 (90.4%)	122 (89.1%)
Censored	13 (9.6%)	15 (10.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	0.9 (0.7, 1.4)
50%	2.6 (2.1, 3.0)	2.1 (1.5, 2.8)
75%	10.3 (5.7, 13.1)	8.8 (5.4, 15.8)
Survival probability (95% CI) at		
Month 6	32.2% (24.3%, 40.3%)	31.7% (24.0%, 39.7%)
Month 12	20.6% (14.1%, 28.1%)	21.5% (14.8%, 29.1%)
Month 18	14.6% (9.0%, 21.4%)	13.7% (8.3%, 20.4%)
Month 24	9.1% (4.8%, 15.2%)	8.2% (4.1%, 14.1%)
Month 30	6.4% (2.9%, 11.9%)	5.5% (2.3%, 10.7%)
Month 36	5.3% (2.2%, 10.6%)	5.5% (2.3%, 10.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.98 (0.758, 1.278)	
p-value of 2-sided stratified log-rank test	0.9366	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	122	122
0	66 (54.1%)	69 (56.6%)
1	19 (15.6%)	17 (13.9%)
2	10 (8.2%)	9 (7.4%)
3	9 (7.4%)	8 (6.6%)
>=4	18 (14.8%)	19 (15.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	51 (89.5%)	42 (89.4%)
Censored	6 (10.5%)	5 (10.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	0.8 (0.8, 1.5)
50%	1.6 (1.4, 2.8)	2.1 (1.4, 3.1)
75%	6.0 (2.8, 11.5)	3.8 (2.8, 16.7)
Survival probability (95% CI) at		
Month 6	23.8% (13.5%, 35.7%)	20.0% (9.9%, 32.6%)
Month 12	13.9% (6.2%, 24.6%)	17.8% (8.3%, 30.1%)
Month 18	7.9% (2.6%, 17.3%)	11.1% (4.1%, 22.1%)
Month 24	5.9% (1.6%, 14.7%)	6.7% (1.7%, 16.4%)
Month 30	5.9% (1.6%, 14.7%)	6.7% (1.7%, 16.4%)
Month 36	NE (NE, NE)	6.7% (1.7%, 16.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.91 (0.589, 1.418)	
p-value of 2-sided stratified log-rank test	0.6898	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	51	42
0	32 (62.7%)	22 (52.4%)
1	7 (13.7%)	5 (11.9%)
2	2 (3.9%)	6 (14.3%)
3	3 (5.9%)	1 (2.4%)
>=4	7 (13.7%)	8 (19.0%)
p-value from Interaction Test[c]	0.9983	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	45 (33.3%)	33 (24.1%)
Censored	90 (66.7%)	104 (75.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.1 (1.4, 16.1)	13.8 (3.7, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	70.7% (62.0%, 77.7%)	79.6% (71.5%, 85.7%)
Month 12	67.7% (58.8%, 75.2%)	75.1% (66.2%, 82.0%)
Month 18	65.2% (55.9%, 73.1%)	72.6% (63.1%, 80.0%)
Month 24	63.9% (54.3%, 71.9%)	71.0% (61.2%, 78.7%)
Month 30	63.9% (54.3%, 71.9%)	71.0% (61.2%, 78.7%)
Month 36	63.9% (54.3%, 71.9%)	71.0% (61.2%, 78.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.69 (0.438, 1.079)	
p-value of 2-sided stratified log-rank test	0.1022	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	45	33
0	25 (55.6%)	17 (51.5%)
1	7 (15.6%)	4 (12.1%)
2	3 (6.7%)	5 (15.2%)
3	3 (6.7%)	0
>=4	7 (15.6%)	7 (21.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	12 (21.1%)	7 (14.9%)
Censored	45 (78.9%)	40 (85.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (0.8, NE)	NE (2.8, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	76.5% (62.2%, 85.9%)	84.3% (69.9%, 92.2%)
Month 12	76.5% (62.2%, 85.9%)	84.3% (69.9%, 92.2%)
Month 18	76.5% (62.2%, 85.9%)	84.3% (69.9%, 92.2%)
Month 24	76.5% (62.2%, 85.9%)	84.3% (69.9%, 92.2%)
Month 30	76.5% (62.2%, 85.9%)	84.3% (69.9%, 92.2%)
Month 36	76.5% (62.2%, 85.9%)	84.3% (69.9%, 92.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Muscular Pain Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.67 (0.260, 1.706)	
p-value of 2-sided stratified log-rank test	0.3961	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	12	7
0	7 (58.3%)	3 (42.9%)
1	0	2 (28.6%)
2	2 (16.7%)	1 (14.3%)
3	0	0
>=4	3 (25.0%)	1 (14.3%)
p-value from Interaction Test[c]	0.9318	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	127 (94.1%)	125 (91.2%)
Censored	8 (5.9%)	12 (8.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (NE, NE)	0.7 (NE, NE)
50%	0.8 (0.7, 0.8)	0.8 (0.7, 0.8)
75%	0.9 (0.9, 1.0)	0.9 (0.8, 1.0)
Survival probability (95% CI) at		
Month 6	3.1% (1.0%, 7.1%)	6.8% (3.3%, 11.9%)
Month 12	3.1% (1.0%, 7.1%)	6.8% (3.3%, 11.9%)
Month 18	3.1% (1.0%, 7.1%)	4.5% (1.4%, 10.8%)
Month 24	3.1% (1.0%, 7.1%)	4.5% (1.4%, 10.8%)
Month 30	3.1% (1.0%, 7.1%)	4.5% (1.4%, 10.8%)
Month 36	3.1% (1.0%, 7.1%)	4.5% (1.4%, 10.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.01 (0.779, 1.299)	
p-value of 2-sided stratified log-rank test	0.8485	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	127	125
0	12 (9.4%)	18 (14.4%)
1	19 (15.0%)	20 (16.0%)
2	12 (9.4%)	10 (8.0%)
3	9 (7.1%)	9 (7.2%)
>=4	75 (59.1%)	68 (54.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	50 (87.7%)	45 (95.7%)
Censored	7 (12.3%)	2 (4.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (0.7, 0.8)	0.7 (0.7, 0.8)
50%	0.8 (0.8, 0.8)	0.8 (0.7, 0.8)
75%	0.9 (0.8, 0.9)	0.9 (0.8, 1.0)
Survival probability (95% CI) at		
Month 6	5.7% (1.5%, 14.1%)	0 (NE, NE)
Month 12	5.7% (1.5%, 14.1%)	0 (NE, NE)
Month 18	5.7% (1.5%, 14.1%)	0 (NE, NE)
Month 24	5.7% (1.5%, 14.1%)	0 (NE, NE)
Month 30	5.7% (1.5%, 14.1%)	0 (NE, NE)
Month 36	NE (NE, NE)	0 (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.85 (0.536, 1.352)	
p-value of 2-sided stratified log-rank test	0.5587	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	50	45
0	8 (16.0%)	7 (15.6%)
1	9 (18.0%)	5 (11.1%)
2	6 (12.0%)	7 (15.6%)
3	4 (8.0%)	2 (4.4%)
>=4	23 (46.0%)	24 (53.3%)
p-value from Interaction Test[c]	0.5447	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	130 (96.3%)	132 (96.4%)
Censored	5 (3.7%)	5 (3.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (NE, NE)	0.7 (NE, NE)
50%	0.8 (0.7, 0.8)	0.8 (0.7, 0.8)
75%	0.9 (0.9, 1.0)	0.9 (0.8, 1.0)
Survival probability (95% CI) at		
Month 6	3.0% (1.0%, 7.0%)	7.4% (3.8%, 12.6%)
Month 12	3.0% (1.0%, 7.0%)	5.8% (2.6%, 10.6%)
Month 18	2.3% (0.6%, 6.0%)	3.1% (1.0%, 7.4%)
Month 24	2.3% (0.6%, 6.0%)	2.1% (0.4%, 6.2%)
Month 30	1.5% (0.3%, 4.9%)	1.0% (0.1%, 4.8%)
Month 36	1.5% (0.3%, 4.9%)	1.0% (0.1%, 4.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.01 (0.787, 1.304)	
p-value of 2-sided stratified log-rank test	0.8027	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	130	132
0	15 (11.5%)	25 (18.9%)
1	19 (14.6%)	20 (15.2%)
2	12 (9.2%)	10 (7.6%)
3	9 (6.9%)	9 (6.8%)
>=4	75 (57.7%)	68 (51.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	55 (96.5%)	45 (95.7%)
Censored	2 (3.5%)	2 (4.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.7 (0.7, 0.8)	0.7 (0.7, 0.8)
50%	0.8 (0.8, 0.8)	0.8 (0.7, 0.8)
75%	0.9 (0.9, 1.0)	0.9 (0.8, 1.0)
Survival probability (95% CI) at		
Month 6	5.4% (1.4%, 13.4%)	0 (NE, NE)
Month 12	3.6% (0.7%, 10.9%)	0 (NE, NE)
Month 18	3.6% (0.7%, 10.9%)	0 (NE, NE)
Month 24	3.6% (0.7%, 10.9%)	0 (NE, NE)
Month 30	1.8% (0.1%, 8.3%)	0 (NE, NE)
Month 36	NE (NE, NE)	0 (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.73 (0.464, 1.145)	
p-value of 2-sided stratified log-rank test	0.1963	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	55	45
0	13 (23.6%)	7 (15.6%)
1	9 (16.4%)	5 (11.1%)
2	6 (10.9%)	7 (15.6%)
3	4 (7.3%)	2 (4.4%)
>=4	23 (41.8%)	24 (53.3%)
p-value from Interaction Test[c]	0.3075	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	10 (7.4%)	9 (6.6%)
Censored	125 (92.6%)	128 (93.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (NE, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	97.5% (92.6%, 99.2%)	98.3% (93.3%, 99.6%)
Month 12	90.9% (83.8%, 95.0%)	92.7% (85.3%, 96.5%)
Month 18	90.9% (83.8%, 95.0%)	90.3% (82.1%, 94.9%)
Month 24	90.9% (83.8%, 95.0%)	90.3% (82.1%, 94.9%)
Month 30	90.9% (83.8%, 95.0%)	90.3% (82.1%, 94.9%)
Month 36	90.9% (83.8%, 95.0%)	90.3% (82.1%, 94.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.89 (0.360, 2.195)	
p-value of 2-sided stratified log-rank test	0.7982	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	10	9
0	2 (20.0%)	6 (66.7%)
1	0	0
2	0	0
3	0	0
>=4	8 (80.0%)	3 (33.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	5 (8.8%)	0
Censored	52 (91.2%)	47 (100%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (7.6, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	93.9% (82.1%, 98.0%)	100% (100%, 100%)
Month 12	87.6% (72.1%, 94.8%)	100% (100%, 100%)
Month 18	87.6% (72.1%, 94.8%)	100% (100%, 100%)
Month 24	87.6% (72.1%, 94.8%)	100% (100%, 100%)
Month 30	87.6% (72.1%, 94.8%)	100% (100%, 100%)
Month 36	87.6% (72.1%, 94.8%)	100% (100%, 100%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Hair Loss Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	- (-, -)	
p-value of 2-sided stratified log-rank test	0.0324	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	5	0
0	5 (100%)	0
1	0	0
2	0	0
3	0	0
>=4	0	0
p-value from Interaction Test[c]	0.9881	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	100 (74.1%)	94 (68.6%)
Censored	35 (25.9%)	43 (31.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.8)	0.7 (0.7, 0.8)
50%	1.4 (1.0, 1.5)	1.4 (1.4, 2.1)
75%	17.1 (2.1, NE)	31.3 (3.7, NE)
Survival probability (95% CI) at		
Month 6	27.2% (19.8%, 35.0%)	31.2% (23.4%, 39.3%)
Month 12	27.2% (19.8%, 35.0%)	30.2% (22.4%, 38.2%)
Month 18	24.6% (17.3%, 32.6%)	27.0% (19.1%, 35.5%)
Month 24	24.6% (17.3%, 32.6%)	27.0% (19.1%, 35.5%)
Month 30	23.1% (15.8%, 31.2%)	27.0% (19.1%, 35.5%)
Month 36	21.2% (13.8%, 29.6%)	24.5% (16.3%, 33.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.12 (0.838, 1.491)	
p-value of 2-sided stratified log-rank test	0.4222	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	100	94
0	38 (38.0%)	33 (35.1%)
1	9 (9.0%)	13 (13.8%)
2	9 (9.0%)	10 (10.6%)
3	11 (11.0%)	6 (6.4%)
>=4	33 (33.0%)	32 (34.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	38 (66.7%)	35 (74.5%)
Censored	19 (33.3%)	12 (25.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.8, 0.9)	0.8 (0.8, 1.4)
50%	1.6 (0.9, 2.9)	2.1 (1.0, 3.5)
75%	NE (2.9, NE)	12.5 (3.5, NE)
Survival probability (95% CI) at		
Month 6	28.5% (16.9%, 41.2%)	28.7% (16.4%, 42.3%)
Month 12	25.3% (14.0%, 38.3%)	26.1% (14.3%, 39.6%)
Month 18	25.3% (14.0%, 38.3%)	20.9% (10.2%, 34.1%)
Month 24	25.3% (14.0%, 38.3%)	20.9% (10.2%, 34.1%)
Month 30	25.3% (14.0%, 38.3%)	20.9% (10.2%, 34.1%)
Month 36	NE (NE, NE)	20.9% (10.2%, 34.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.05 (0.657, 1.683)	
p-value of 2-sided stratified log-rank test	0.8267	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	38	35
0	11 (28.9%)	11 (31.4%)
1	4 (10.5%)	12 (34.3%)
2	6 (15.8%)	4 (11.4%)
3	3 (7.9%)	1 (2.9%)
>=4	14 (36.8%)	7 (20.0%)
p-value from Interaction Test[c]	0.6969	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	114 (84.4%)	117 (85.4%)
Censored	21 (15.6%)	20 (14.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 0.8)	0.7 (0.7, 0.8)
50%	1.4 (1.0, 1.5)	1.4 (1.4, 2.1)
75%	9.7 (2.1, 24.2)	12.6 (3.8, 17.3)
Survival probability (95% CI) at		
Month 6	27.3% (20.0%, 35.0%)	31.1% (23.5%, 39.0%)
Month 12	24.0% (17.1%, 31.6%)	26.2% (19.0%, 33.9%)
Month 18	21.2% (14.5%, 28.7%)	16.3% (10.5%, 23.2%)
Month 24	18.3% (12.0%, 25.6%)	13.3% (8.0%, 20.0%)
Month 30	15.4% (9.6%, 22.5%)	12.2% (7.1%, 18.9%)
Month 36	13.1% (7.6%, 20.1%)	11.1% (6.2%, 17.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.02 (0.783, 1.333)	
p-value of 2-sided stratified log-rank test	0.8617	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	114	117
0	52 (45.6%)	56 (47.9%)
1	9 (7.9%)	13 (11.1%)
2	9 (7.9%)	10 (8.5%)
3	11 (9.6%)	6 (5.1%)
>=4	33 (28.9%)	32 (27.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	49 (86.0%)	39 (83.0%)
Censored	8 (14.0%)	8 (17.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.8, 0.9)	0.8 (0.8, 1.4)
50%	1.6 (0.9, 2.9)	2.1 (1.0, 3.5)
75%	5.3 (2.9, 15.3)	12.5 (3.5, 32.9)
Survival probability (95% CI) at		
Month 6	24.0% (13.7%, 35.8%)	28.9% (16.6%, 42.4%)
Month 12	20.3% (10.9%, 31.7%)	26.7% (14.9%, 40.0%)
Month 18	12.9% (5.7%, 23.2%)	19.8% (9.6%, 32.5%)
Month 24	12.9% (5.7%, 23.2%)	17.3% (7.9%, 29.7%)
Month 30	11.1% (4.5%, 20.9%)	17.3% (7.9%, 29.7%)
Month 36	NE (NE, NE)	9.2% (2.2%, 22.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.11 (0.721, 1.716)	
p-value of 2-sided stratified log-rank test	0.6143	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	49	39
0	22 (44.9%)	15 (38.5%)
1	4 (8.2%)	12 (30.8%)
2	6 (12.2%)	4 (10.3%)
3	3 (6.1%)	1 (2.6%)
>=4	14 (28.6%)	7 (17.9%)
p-value from Interaction Test[c]	0.7723	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	18 (13.3%)	16 (11.7%)
Censored	117 (86.7%)	121 (88.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (28.7, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	89.8% (83.1%, 94.0%)	88.8% (81.8%, 93.2%)
Month 12	87.9% (80.6%, 92.5%)	86.8% (79.2%, 91.7%)
Month 18	87.9% (80.6%, 92.5%)	86.8% (79.2%, 91.7%)
Month 24	85.1% (76.8%, 90.6%)	86.8% (79.2%, 91.7%)
Month 30	83.2% (74.0%, 89.4%)	86.8% (79.2%, 91.7%)
Month 36	83.2% (74.0%, 89.4%)	86.8% (79.2%, 91.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.94 (0.477, 1.839)	
p-value of 2-sided stratified log-rank test	0.8467	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	18	16
0	10 (55.6%)	4 (25.0%)
1	4 (22.2%)	3 (18.8%)
2	0	5 (31.3%)
3	0	1 (6.3%)
>=4	4 (22.2%)	3 (18.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	5 (8.8%)	4 (8.5%)
Censored	52 (91.2%)	43 (91.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (11.4, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	92.1% (80.3%, 97.0%)	90.9% (77.6%, 96.5%)
Month 12	88.9% (74.8%, 95.4%)	90.9% (77.6%, 96.5%)
Month 18	88.9% (74.8%, 95.4%)	90.9% (77.6%, 96.5%)
Month 24	88.9% (74.8%, 95.4%)	90.9% (77.6%, 96.5%)
Month 30	88.9% (74.8%, 95.4%)	90.9% (77.6%, 96.5%)
Month 36	88.9% (74.8%, 95.4%)	90.9% (77.6%, 96.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Taste Change Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.94 (0.249, 3.575)	
p-value of 2-sided stratified log-rank test	0.9315	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	5	4
0	3 (60.0%)	3 (75.0%)
1	1 (20.0%)	0
2	1 (20.0%)	1 (25.0%)
3	0	0
>=4	0	0
p-value from Interaction Test[c]	0.9552	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2702 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	43 (44.3%)	33 (39.3%)
Censored	54 (55.7%)	51 (60.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.5 (2.1, 7.0)	3.7 (2.8, 8.3)
50%	25.3 (10.5, NE)	NE (9.6, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	68.7% (58.2%, 77.1%)	71.3% (59.7%, 80.1%)
Month 12	60.6% (49.4%, 70.0%)	60.2% (47.8%, 70.5%)
Month 18	53.9% (42.2%, 64.2%)	58.3% (45.7%, 68.9%)
Month 24	50.3% (38.5%, 61.1%)	54.1% (41.2%, 65.3%)
Month 30	46.4% (34.4%, 57.6%)	51.7% (38.6%, 63.4%)
Month 36	46.4% (34.4%, 57.6%)	51.7% (38.6%, 63.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2702_eq5d_ttiw_age.sas, Output: t_2_2702_eq5d_ttiw_age.rtf, Generated on: 30AUG2024 16:22, Data Cutoff Date: 22SEP2023

Table 2.2702 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.15 (0.728, 1.829)	
p-value of 2-sided stratified log-rank test	0.5392	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	43	33
0	26 (60.5%)	23 (69.7%)
1	5 (11.6%)	2 (6.1%)
2	4 (9.3%)	2 (6.1%)
3	3 (7.0%)	1 (3.0%)
>=4	5 (11.6%)	5 (15.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2702_eq5d_ttiw_age.sas, Output: t_2_2702_eq5d_ttiw_age.rtf, Generated on: 30AUG2024 16:22, Data Cutoff Date: 22SEP2023

Table 2.2702 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	56 (58.9%)	56 (56.0%)
Censored	39 (41.1%)	44 (44.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.4, 2.8)	3.0 (2.1, 4.2)
50%	5.4 (3.5, 12.9)	14.8 (6.7, 27.9)
75%	NE (15.4, NE)	38.0 (30.7, NE)
Survival probability (95% CI) at		
Month 6	48.0% (37.1%, 58.1%)	62.5% (51.8%, 71.4%)
Month 12	42.0% (31.1%, 52.4%)	53.4% (42.4%, 63.3%)
Month 18	33.9% (23.4%, 44.7%)	45.0% (33.7%, 55.7%)
Month 24	31.8% (21.3%, 42.8%)	41.4% (30.1%, 52.4%)
Month 30	31.8% (21.3%, 42.8%)	37.5% (26.2%, 48.8%)
Month 36	31.8% (21.3%, 42.8%)	27.2% (16.1%, 39.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2702_eq5d_ttiw_age.sas, Output: t_2_2702_eq5d_ttiw_age.rtf, Generated on: 30AUG2024 16:22, Data Cutoff Date: 22SEP2023

Table 2.2702 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.23 (0.843, 1.796)	
p-value of 2-sided stratified log-rank test	0.2798	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	56	56
0	32 (57.1%)	36 (64.3%)
1	11 (19.6%)	7 (12.5%)
2	5 (8.9%)	5 (8.9%)
3	3 (5.4%)	4 (7.1%)
>=4	5 (8.9%)	4 (7.1%)
p-value from Interaction Test[c]	0.8838	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2702_eq5d_ttiw_age.sas, Output: t_2_2702_eq5d_ttiw_age.rtf, Generated on: 30AUG2024 16:22, Data Cutoff Date: 22SEP2023

Table 2.2702 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	66 (68.0%)	53 (63.1%)
Censored	31 (32.0%)	31 (36.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.5 (2.1, 5.3)	3.5 (2.8, 6.3)
50%	13.2 (7.0, 18.7)	13.3 (8.3, 19.4)
75%	NE (25.3, NE)	NE (28.2, NE)
Survival probability (95% CI) at		
Month 6	65.1% (54.6%, 73.8%)	66.4% (54.9%, 75.6%)
Month 12	50.7% (40.1%, 60.3%)	54.5% (42.9%, 64.7%)
Month 18	41.3% (31.1%, 51.3%)	42.3% (31.1%, 53.0%)
Month 24	36.5% (26.6%, 46.4%)	36.6% (25.9%, 47.4%)
Month 30	30.4% (21.1%, 40.2%)	33.7% (23.2%, 44.4%)
Month 36	25.7% (16.8%, 35.6%)	31.3% (20.8%, 42.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2702_eq5d_ttiw_age.sas, Output: t_2_2702_eq5d_ttiw_age.rtf, Generated on: 30AUG2024 16:22, Data Cutoff Date: 22SEP2023

Table 2.2702 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.14 (0.793, 1.650)	
p-value of 2-sided stratified log-rank test	0.4673	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	66	53
0	49 (74.2%)	43 (81.1%)
1	5 (7.6%)	2 (3.8%)
2	4 (6.1%)	2 (3.8%)
3	3 (4.5%)	1 (1.9%)
>=4	5 (7.6%)	5 (9.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2702_eq5d_ttiw_age.sas, Output: t_2_2702_eq5d_ttiw_age.rtf, Generated on: 30AUG2024 16:22, Data Cutoff Date: 22SEP2023

Table 2.2702 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	72 (75.8%)	81 (81.0%)
Censored	23 (24.2%)	19 (19.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.4, 2.4)	3.0 (2.1, 4.2)
50%	4.4 (3.1, 10.2)	9.4 (6.1, 14.4)
75%	19.6 (12.9, 37.5)	27.9 (17.3, 36.1)
Survival probability (95% CI) at		
Month 6	46.0% (35.5%, 55.9%)	61.2% (50.8%, 70.1%)
Month 12	37.3% (27.3%, 47.3%)	44.4% (34.3%, 54.0%)
Month 18	26.0% (17.1%, 35.7%)	31.7% (22.7%, 41.1%)
Month 24	23.2% (14.8%, 32.8%)	27.4% (18.9%, 36.6%)
Month 30	20.5% (12.5%, 29.9%)	24.0% (15.9%, 32.9%)
Month 36	19.0% (11.3%, 28.3%)	16.7% (9.6%, 25.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2702_eq5d_ttiw_age.sas, Output: t_2_2702_eq5d_ttiw_age.rtf, Generated on: 30AUG2024 16:22, Data Cutoff Date: 22SEP2023

Table 2.2702 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.14 (0.828, 1.579)	
p-value of 2-sided stratified log-rank test	0.4084	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	72	81
0	48 (66.7%)	61 (75.3%)
1	11 (15.3%)	7 (8.6%)
2	5 (6.9%)	5 (6.2%)
3	3 (4.2%)	4 (4.9%)
>=4	5 (6.9%)	4 (4.9%)
p-value from Interaction Test[c]	0.9352	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2702_eq5d_ttiw_age.sas, Output: t_2_2702_eq5d_ttiw_age.rtf, Generated on: 30AUG2024 16:22, Data Cutoff Date: 22SEP2023

Table 2.2702 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	30 (30.9%)	26 (31.0%)
Censored	67 (69.1%)	58 (69.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	5.6 (2.3, 18.9)	3.7 (1.4, 34.1)
50%	NE (NE, NE)	NE (34.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	72.6% (62.1%, 80.6%)	69.7% (57.9%, 78.7%)
Month 12	68.6% (57.7%, 77.2%)	68.1% (56.2%, 77.4%)
Month 18	66.9% (55.7%, 75.8%)	66.1% (53.9%, 75.8%)
Month 24	65.0% (53.5%, 74.4%)	66.1% (53.9%, 75.8%)
Month 30	65.0% (53.5%, 74.4%)	66.1% (53.9%, 75.8%)
Month 36	65.0% (53.5%, 74.4%)	61.7% (47.1%, 73.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2702_eq5d_ttiw_age.sas, Output: t_2_2702_eq5d_ttiw_age.rtf, Generated on: 30AUG2024 16:22, Data Cutoff Date: 22SEP2023

Table 2.2702 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.06 (0.624, 1.814)	
p-value of 2-sided stratified log-rank test	0.8299	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	30	26
0	10 (33.3%)	11 (42.3%)
1	5 (16.7%)	4 (15.4%)
2	3 (10.0%)	4 (15.4%)
3	3 (10.0%)	0
>=4	9 (30.0%)	7 (26.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2702_eq5d_ttiw_age.sas, Output: t_2_2702_eq5d_ttiw_age.rtf, Generated on: 30AUG2024 16:22, Data Cutoff Date: 22SEP2023

Table 2.2702 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	35 (36.8%)	32 (32.0%)
Censored	60 (63.2%)	68 (68.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.5 (1.0, 7.5)	2.8 (1.4, 11.8)
50%	NE (12.7, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	69.6% (58.6%, 78.2%)	71.6% (61.3%, 79.6%)
Month 12	62.5% (50.9%, 72.1%)	65.8% (54.7%, 74.7%)
Month 18	60.8% (49.1%, 70.6%)	64.1% (52.9%, 73.3%)
Month 24	54.2% (41.6%, 65.3%)	64.1% (52.9%, 73.3%)
Month 30	54.2% (41.6%, 65.3%)	64.1% (52.9%, 73.3%)
Month 36	54.2% (41.6%, 65.3%)	64.1% (52.9%, 73.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2702_eq5d_ttiw_age.sas, Output: t_2_2702_eq5d_ttiw_age.rtf, Generated on: 30AUG2024 16:22, Data Cutoff Date: 22SEP2023

Table 2.2702 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.81 (0.497, 1.309)	
p-value of 2-sided stratified log-rank test	0.3819	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	35	32
0	16 (45.7%)	18 (56.3%)
1	9 (25.7%)	1 (3.1%)
2	2 (5.7%)	4 (12.5%)
3	0	1 (3.1%)
>=4	8 (22.9%)	8 (25.0%)
p-value from Interaction Test[c]	0.5291	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2702_eq5d_ttiw_age.sas, Output: t_2_2702_eq5d_ttiw_age.rtf, Generated on: 30AUG2024 16:22, Data Cutoff Date: 22SEP2023

Table 2.2802 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	69 (51.1%)	59 (43.1%)
Censored	66 (48.9%)	78 (56.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.7, 4.1)	4.0 (2.8, 8.3)
50%	14.8 (8.2, 37.5)	29.3 (14.8, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	61.1% (52.1%, 69.0%)	71.2% (62.4%, 78.3%)
Month 12	53.5% (44.2%, 61.9%)	62.4% (53.0%, 70.5%)
Month 18	46.9% (37.4%, 55.8%)	55.1% (45.1%, 64.1%)
Month 24	44.3% (34.8%, 53.4%)	51.1% (40.9%, 60.5%)
Month 30	41.5% (31.8%, 50.8%)	49.6% (39.3%, 59.1%)
Month 36	41.5% (31.8%, 50.8%)	44.6% (33.9%, 54.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2802_eq5d_ttiw_reg.sas, Output: t_2_2802_eq5d_ttiw_reg.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2802 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.26 (0.887, 1.789)	
p-value of 2-sided stratified log-rank test	0.1962	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	69	59
0	41 (59.4%)	45 (76.3%)
1	9 (13.0%)	2 (3.4%)
2	7 (10.1%)	4 (6.8%)
3	5 (7.2%)	5 (8.5%)
>=4	7 (10.1%)	3 (5.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2802_eq5d_ttiw_reg.sas, Output: t_2_2802_eq5d_ttiw_reg.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2802 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	30 (52.6%)	30 (63.8%)
Censored	27 (47.4%)	17 (36.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.3 (0.9, 3.5)	2.1 (1.0, 2.9)
50%	10.0 (3.5, 20.0)	6.3 (2.8, 27.5)
75%	NE (16.1, NE)	31.3 (9.7, NE)
Survival probability (95% CI) at		
Month 6	52.8% (38.2%, 65.5%)	53.0% (37.4%, 66.3%)
Month 12	46.9% (32.0%, 60.5%)	39.7% (24.9%, 54.2%)
Month 18	36.7% (21.8%, 51.6%)	39.7% (24.9%, 54.2%)
Month 24	33.0% (18.5%, 48.3%)	36.1% (21.4%, 51.0%)
Month 30	33.0% (18.5%, 48.3%)	28.1% (14.2%, 43.9%)
Month 36	33.0% (18.5%, 48.3%)	24.1% (11.0%, 40.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2802_eq5d_ttiw_reg.sas, Output: t_2_2802_eq5d_ttiw_reg.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2802 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.88 (0.521, 1.478)	
p-value of 2-sided stratified log-rank test	0.6238	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	30	30
0	17 (56.7%)	14 (46.7%)
1	7 (23.3%)	7 (23.3%)
2	2 (6.7%)	3 (10.0%)
3	1 (3.3%)	0
>=4	3 (10.0%)	6 (20.0%)
p-value from Interaction Test[c]	0.2637	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2802_eq5d_ttiw_reg.sas, Output: t_2_2802_eq5d_ttiw_reg.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2802 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	92 (68.1%)	98 (71.5%)
Censored	43 (31.9%)	39 (28.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.7 (1.6, 4.1)	3.7 (2.8, 5.9)
50%	11.8 (6.8, 16.8)	12.6 (9.4, 16.3)
75%	36.2 (24.6, NE)	36.1 (23.5, NE)
Survival probability (95% CI) at		
Month 6	60.3% (51.4%, 68.1%)	67.7% (59.1%, 74.9%)
Month 12	48.5% (39.5%, 56.9%)	52.8% (43.9%, 60.9%)
Month 18	38.8% (30.2%, 47.3%)	37.6% (29.2%, 45.9%)
Month 24	35.0% (26.6%, 43.6%)	32.7% (24.7%, 40.9%)
Month 30	29.4% (21.3%, 37.8%)	30.1% (22.3%, 38.2%)
Month 36	26.1% (18.4%, 34.5%)	25.9% (18.4%, 34.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2802_eq5d_ttiw_reg.sas, Output: t_2_2802_eq5d_ttiw_reg.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2802 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.05 (0.786, 1.394)	
p-value of 2-sided stratified log-rank test	0.7544	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	92	98
0	64 (69.6%)	84 (85.7%)
1	9 (9.8%)	2 (2.0%)
2	7 (7.6%)	4 (4.1%)
3	5 (5.4%)	5 (5.1%)
>=4	7 (7.6%)	3 (3.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2802_eq5d_ttiw_reg.sas, Output: t_2_2802_eq5d_ttiw_reg.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2802 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	46 (80.7%)	36 (76.6%)
Censored	11 (19.3%)	11 (23.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.2 (1.1, 2.8)	2.1 (1.0, 2.9)
50%	5.0 (2.8, 10.0)	6.1 (2.8, 16.7)
75%	15.4 (9.6, NE)	27.9 (10.3, NE)
Survival probability (95% CI) at		
Month 6	44.9% (31.4%, 57.4%)	51.1% (35.8%, 64.5%)
Month 12	33.6% (21.5%, 46.2%)	37.4% (23.5%, 51.3%)
Month 18	22.4% (12.4%, 34.2%)	32.7% (19.6%, 46.6%)
Month 24	18.7% (9.6%, 30.0%)	27.9% (15.6%, 41.6%)
Month 30	16.8% (8.3%, 27.9%)	22.3% (11.1%, 35.8%)
Month 36	14.0% (6.1%, 25.2%)	16.3% (6.7%, 29.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2802_eq5d_ttiw_reg.sas, Output: t_2_2802_eq5d_ttiw_reg.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2802 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.10 (0.700, 1.713)	
p-value of 2-sided stratified log-rank test	0.6882	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	46	36
0	33 (71.7%)	20 (55.6%)
1	7 (15.2%)	7 (19.4%)
2	2 (4.3%)	3 (8.3%)
3	1 (2.2%)	0
>=4	3 (6.5%)	6 (16.7%)
p-value from Interaction Test[c]	0.7877	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2802_eq5d_ttiw_reg.sas, Output: t_2_2802_eq5d_ttiw_reg.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2802 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	49 (36.3%)	41 (29.9%)
Censored	86 (63.7%)	96 (70.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.8 (1.4, 7.5)	4.3 (2.1, 14.1)
50%	NE (23.0, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	71.2% (62.4%, 78.2%)	73.1% (64.5%, 80.0%)
Month 12	65.8% (56.7%, 73.4%)	68.9% (59.7%, 76.4%)
Month 18	63.5% (54.2%, 71.5%)	66.4% (56.8%, 74.3%)
Month 24	58.1% (48.2%, 66.9%)	66.4% (56.8%, 74.3%)
Month 30	58.1% (48.2%, 66.9%)	66.4% (56.8%, 74.3%)
Month 36	58.1% (48.2%, 66.9%)	63.5% (52.6%, 72.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2802_eq5d_ttiw_reg.sas, Output: t_2_2802_eq5d_ttiw_reg.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2802 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.80 (0.524, 1.214)	
p-value of 2-sided stratified log-rank test	0.2912	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	49	41
0	19 (38.8%)	20 (48.8%)
1	11 (22.4%)	5 (12.2%)
2	4 (8.2%)	6 (14.6%)
3	1 (2.0%)	0
>=4	14 (28.6%)	10 (24.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2802_eq5d_ttiw_reg.sas, Output: t_2_2802_eq5d_ttiw_reg.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2802 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	16 (28.1%)	17 (36.2%)
Censored	41 (71.9%)	30 (63.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	5.6 (2.3, NE)	1.5 (0.8, 8.5)
50%	NE (9.8, NE)	NE (5.6, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	70.3% (54.9%, 81.4%)	63.8% (47.8%, 76.1%)
Month 12	64.3% (48.0%, 76.7%)	61.1% (45.0%, 73.9%)
Month 18	64.3% (48.0%, 76.7%)	61.1% (45.0%, 73.9%)
Month 24	64.3% (48.0%, 76.7%)	61.1% (45.0%, 73.9%)
Month 30	64.3% (48.0%, 76.7%)	61.1% (45.0%, 73.9%)
Month 36	64.3% (48.0%, 76.7%)	61.1% (45.0%, 73.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2802_eq5d_ttiw_reg.sas, Output: t_2_2802_eq5d_ttiw_reg.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2802 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.41 (0.695, 2.850)	
p-value of 2-sided stratified log-rank test	0.3429	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	16	17
0	7 (43.8%)	9 (52.9%)
1	3 (18.8%)	0
2	1 (6.3%)	2 (11.8%)
3	2 (12.5%)	1 (5.9%)
>=4	3 (18.8%)	5 (29.4%)
p-value from Interaction Test[c]	0.1619	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2802_eq5d_ttiw_reg.sas, Output: t_2_2802_eq5d_ttiw_reg.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	43 (47.8%)	41 (47.1%)
Censored	47 (52.2%)	46 (52.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.2 (1.5, 3.7)	3.3 (2.1, 6.7)
50%	15.2 (4.2, NE)	19.1 (9.7, NE)
75%	NE (NE, NE)	NE (38.0, NE)
Survival probability (95% CI) at		
Month 6	59.0% (47.7%, 68.6%)	69.5% (58.3%, 78.3%)
Month 12	52.9% (41.4%, 63.1%)	58.7% (46.6%, 68.9%)
Month 18	49.7% (38.1%, 60.2%)	52.2% (39.5%, 63.5%)
Month 24	45.7% (33.9%, 56.7%)	45.4% (32.4%, 57.6%)
Month 30	45.7% (33.9%, 56.7%)	40.6% (27.6%, 53.2%)
Month 36	45.7% (33.9%, 56.7%)	40.6% (27.6%, 53.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2902_eq5d_ttiw_dstat.sas, Output: t_2_2902_eq5d_ttiw_dstat.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.06 (0.693, 1.635)	
p-value of 2-sided stratified log-rank test	0.7736	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	43	41
0	24 (55.8%)	25 (61.0%)
1	7 (16.3%)	3 (7.3%)
2	4 (9.3%)	5 (12.2%)
3	3 (7.0%)	3 (7.3%)
>=4	5 (11.6%)	5 (12.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2902_eq5d_ttiw_dstat.sas, Output: t_2_2902_eq5d_ttiw_dstat.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	24 (68.6%)	14 (42.4%)
Censored	11 (31.4%)	19 (57.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.4, 4.6)	3.5 (2.2, 12.8)
50%	10.3 (3.9, 18.2)	31.3 (4.0, NE)
75%	37.5 (14.1, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	57.1% (39.3%, 71.5%)	64.9% (44.5%, 79.4%)
Month 12	47.9% (30.5%, 63.3%)	61.3% (41.0%, 76.4%)
Month 18	34.2% (18.6%, 50.4%)	57.5% (37.3%, 73.2%)
Month 24	30.8% (15.9%, 47.0%)	53.6% (33.7%, 70.0%)
Month 30	30.8% (15.9%, 47.0%)	53.6% (33.7%, 70.0%)
Month 36	30.8% (15.9%, 47.0%)	48.3% (28.1%, 65.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2902_eq5d_ttiw_dstat.sas, Output: t_2_2902_eq5d_ttiw_dstat.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.70 (0.863, 3.346)	
p-value of 2-sided stratified log-rank test	0.1202	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	24	14
0	16 (66.7%)	8 (57.1%)
1	4 (16.7%)	1 (7.1%)
2	2 (8.3%)	2 (14.3%)
3	1 (4.2%)	1 (7.1%)
>=4	1 (4.2%)	2 (14.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2902_eq5d_ttiw_dstat.sas, Output: t_2_2902_eq5d_ttiw_dstat.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	32 (47.8%)	34 (53.1%)
Censored	35 (52.2%)	30 (46.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.5, 4.4)	3.0 (1.2, 5.6)
50%	12.9 (4.4, 27.9)	14.8 (5.6, 30.9)
75%	NE (25.3, NE)	NE (30.7, NE)
Survival probability (95% CI) at		
Month 6	59.3% (45.6%, 70.7%)	63.1% (49.6%, 74.0%)
Month 12	51.8% (37.5%, 64.4%)	50.6% (36.6%, 62.9%)
Month 18	42.9% (28.2%, 56.8%)	45.4% (31.3%, 58.4%)
Month 24	42.9% (28.2%, 56.8%)	45.4% (31.3%, 58.4%)
Month 30	34.3% (19.3%, 49.9%)	41.6% (27.1%, 55.4%)
Month 36	34.3% (19.3%, 49.9%)	30.2% (16.2%, 45.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
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Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.05 (0.646, 1.713)	
p-value of 2-sided stratified log-rank test	0.8355	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	32	34
0	18 (56.3%)	26 (76.5%)
1	5 (15.6%)	5 (14.7%)
2	3 (9.4%)	0
3	2 (6.3%)	1 (2.9%)
>=4	4 (12.5%)	2 (5.9%)
p-value from Interaction Test[c]	0.3654	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
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Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	61 (67.8%)	65 (74.7%)
Censored	29 (32.2%)	22 (25.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.2 (1.5, 3.5)	3.4 (2.1, 6.1)
50%	10.0 (4.1, 19.6)	12.6 (7.9, 17.3)
75%	36.2 (24.3, NE)	27.9 (18.2, NE)
Survival probability (95% CI) at		
Month 6	56.4% (45.4%, 66.1%)	67.1% (56.0%, 76.0%)
Month 12	45.1% (34.3%, 55.3%)	52.3% (41.1%, 62.4%)
Month 18	39.9% (29.3%, 50.2%)	35.7% (25.5%, 46.1%)
Month 24	35.8% (25.5%, 46.1%)	28.1% (18.7%, 38.1%)
Month 30	31.6% (21.8%, 42.0%)	24.2% (15.5%, 34.0%)
Month 36	26.5% (17.0%, 36.9%)	22.6% (14.1%, 32.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
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Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.00 (0.704, 1.419)	
p-value of 2-sided stratified log-rank test	0.9954	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	61	65
0	42 (68.9%)	49 (75.4%)
1	7 (11.5%)	3 (4.6%)
2	4 (6.6%)	5 (7.7%)
3	3 (4.9%)	3 (4.6%)
>=4	5 (8.2%)	5 (7.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
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Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	27 (77.1%)	18 (54.5%)
Censored	8 (22.9%)	15 (45.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.4, 4.6)	3.5 (2.2, 7.4)
50%	10.3 (3.9, 16.5)	23.5 (3.8, 39.1)
75%	31.2 (14.1, NE)	39.1 (36.1, NE)
Survival probability (95% CI) at		
Month 6	57.1% (39.3%, 71.5%)	62.1% (42.1%, 76.9%)
Month 12	48.4% (31.2%, 63.6%)	58.6% (38.8%, 74.0%)
Month 18	30.3% (16.0%, 45.9%)	51.7% (32.5%, 67.9%)
Month 24	27.2% (13.7%, 42.7%)	48.3% (29.5%, 64.8%)
Month 30	27.2% (13.7%, 42.7%)	48.3% (29.5%, 64.8%)
Month 36	23.8% (11.1%, 39.2%)	43.9% (25.4%, 61.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
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Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.48 (0.804, 2.719)	
p-value of 2-sided stratified log-rank test	0.2051	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	27	18
0	19 (70.4%)	12 (66.7%)
1	4 (14.8%)	1 (5.6%)
2	2 (7.4%)	2 (11.1%)
3	1 (3.7%)	1 (5.6%)
>=4	1 (3.7%)	2 (11.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
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Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	50 (74.6%)	51 (79.7%)
Censored	17 (25.4%)	13 (20.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.3 (1.4, 4.2)	2.8 (1.0, 4.0)
50%	7.0 (4.4, 13.2)	9.3 (4.7, 12.2)
75%	19.5 (13.2, NE)	29.3 (13.2, NE)
Survival probability (95% CI) at		
Month 6	54.1% (41.0%, 65.4%)	59.4% (46.3%, 70.2%)
Month 12	40.2% (27.9%, 52.2%)	39.6% (27.5%, 51.4%)
Month 18	27.8% (17.0%, 39.5%)	29.7% (18.9%, 41.3%)
Month 24	23.9% (13.9%, 35.5%)	27.7% (17.2%, 39.3%)
Month 30	15.9% (7.7%, 26.8%)	23.5% (13.5%, 35.0%)
Month 36	15.9% (7.7%, 26.8%)	11.4% (3.2%, 25.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
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Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.10 (0.746, 1.636)	
p-value of 2-sided stratified log-rank test	0.6187	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	50	51
0	36 (72.0%)	43 (84.3%)
1	5 (10.0%)	5 (9.8%)
2	3 (6.0%)	0
3	2 (4.0%)	1 (2.0%)
>=4	4 (8.0%)	2 (3.9%)
p-value from Interaction Test[c]	0.4541	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
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Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	34 (37.8%)	27 (31.0%)
Censored	56 (62.2%)	60 (69.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.0, 7.0)	5.1 (1.6, 34.1)
50%	NE (12.7, NE)	NE (34.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	68.4% (57.4%, 77.2%)	74.8% (63.9%, 82.8%)
Month 12	62.5% (50.9%, 72.1%)	69.6% (57.9%, 78.7%)
Month 18	58.9% (46.9%, 69.0%)	65.7% (53.3%, 75.5%)
Month 24	56.7% (44.4%, 67.2%)	65.7% (53.3%, 75.5%)
Month 30	56.7% (44.4%, 67.2%)	65.7% (53.3%, 75.5%)
Month 36	56.7% (44.4%, 67.2%)	60.2% (44.3%, 72.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
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Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.78 (0.468, 1.287)	
p-value of 2-sided stratified log-rank test	0.3253	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	34	27
0	14 (41.2%)	19 (70.4%)
1	8 (23.5%)	1 (3.7%)
2	1 (2.9%)	3 (11.1%)
3	3 (8.8%)	0
>=4	8 (23.5%)	4 (14.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
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Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	10 (28.6%)	7 (21.2%)
Censored	25 (71.4%)	26 (78.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	21.9 (3.8, NE)	8.5 (1.4, NE)
50%	NE (21.9, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	79.1% (61.0%, 89.4%)	79.4% (59.8%, 90.2%)
Month 12	75.8% (57.3%, 87.1%)	75.0% (54.3%, 87.3%)
Month 18	75.8% (57.3%, 87.1%)	75.0% (54.3%, 87.3%)
Month 24	65.0% (43.1%, 80.2%)	75.0% (54.3%, 87.3%)
Month 30	65.0% (43.1%, 80.2%)	75.0% (54.3%, 87.3%)
Month 36	65.0% (43.1%, 80.2%)	75.0% (54.3%, 87.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
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Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.92 (0.349, 2.427)	
p-value of 2-sided stratified log-rank test	0.8650	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	10	7
0	6 (60.0%)	3 (42.9%)
1	1 (10.0%)	1 (14.3%)
2	1 (10.0%)	1 (14.3%)
3	0	0
>=4	2 (20.0%)	2 (28.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2902_eq5d_ttiw_dstat.sas, Output: t_2_2902_eq5d_ttiw_dstat.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	21 (31.3%)	24 (37.5%)
Censored	46 (68.7%)	40 (62.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	5.1 (1.1, 18.9)	1.6 (1.0, 5.6)
50%	NE (9.8, NE)	NE (5.6, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	70.5% (56.7%, 80.6%)	61.2% (47.4%, 72.3%)
Month 12	64.1% (49.8%, 75.3%)	59.2% (45.4%, 70.6%)
Month 18	64.1% (49.8%, 75.3%)	59.2% (45.4%, 70.6%)
Month 24	60.9% (45.9%, 73.0%)	59.2% (45.4%, 70.6%)
Month 30	60.9% (45.9%, 73.0%)	59.2% (45.4%, 70.6%)
Month 36	60.9% (45.9%, 73.0%)	59.2% (45.4%, 70.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2902_eq5d_ttiw_dstat.sas, Output: t_2_2902_eq5d_ttiw_dstat.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.2902 Kaplan Meier Analysis of EQ-5D-5L Visual Analogue Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EQ-5D-5L VAS Score 15-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.25 (0.690, 2.261)	
p-value of 2-sided stratified log-rank test	0.4665	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	21	24
0	6 (28.6%)	7 (29.2%)
1	5 (23.8%)	3 (12.5%)
2	3 (14.3%)	4 (16.7%)
3	0	1 (4.2%)
>=4	7 (33.3%)	9 (37.5%)
p-value from Interaction Test[c]	0.4754	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For EQ-VAS, the scale score change from baseline is categorized as follows: Improvement: change from baseline >= 15; Stable: -15 < change from baseline < 15; Deterioration: change from baseline <= -15.
Program: t_2_2902_eq5d_ttiw_dstat.sas, Output: t_2_2902_eq5d_ttiw_dstat.rtf, Generated on: 30AUG2024 16:21, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	68 (70.1%)	55 (65.5%)
Censored	29 (29.9%)	29 (34.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.4, 2.8)	1.4 (0.7, 2.1)
50%	3.5 (2.8, 4.4)	3.5 (2.1, 9.6)
75%	29.9 (11.1, NE)	40.3 (10.2, NE)
Survival probability (95% CI) at		
Month 6	37.7% (27.9%, 47.5%)	43.2% (32.1%, 53.8%)
Month 12	33.7% (24.0%, 43.5%)	31.4% (20.9%, 42.4%)
Month 18	32.1% (22.6%, 42.1%)	31.4% (20.9%, 42.4%)
Month 24	28.7% (19.3%, 38.8%)	29.0% (18.5%, 40.3%)
Month 30	23.4% (14.4%, 33.6%)	26.4% (16.0%, 37.9%)
Month 36	17.5% (7.4%, 31.2%)	26.4% (16.0%, 37.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.97 (0.677, 1.390)	
p-value of 2-sided stratified log-rank test	0.8738	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	68	55
0	40 (58.8%)	34 (61.8%)
1	9 (13.2%)	7 (12.7%)
2	9 (13.2%)	4 (7.3%)
3	3 (4.4%)	1 (1.8%)
>=4	7 (10.3%)	9 (16.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	69 (72.6%)	74 (74.0%)
Censored	26 (27.4%)	26 (26.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.0)	1.1 (0.8, 2.0)
50%	3.1 (2.1, 4.1)	4.2 (2.2, 7.4)
75%	12.9 (5.8, 30.3)	14.7 (9.1, 27.7)
Survival probability (95% CI) at		
Month 6	34.8% (25.0%, 44.9%)	42.6% (32.4%, 52.4%)
Month 12	28.8% (19.4%, 38.9%)	28.4% (19.0%, 38.5%)
Month 18	24.0% (15.1%, 34.1%)	19.0% (10.7%, 29.3%)
Month 24	16.8% (8.6%, 27.4%)	16.9% (8.9%, 27.1%)
Month 30	16.8% (8.6%, 27.4%)	11.3% (4.4%, 21.9%)
Month 36	11.5% (4.5%, 22.2%)	4.2% (0.5%, 15.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.97 (0.694, 1.361)	
p-value of 2-sided stratified log-rank test	0.8801	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	69	74
0	39 (56.5%)	44 (59.5%)
1	9 (13.0%)	13 (17.6%)
2	9 (13.0%)	1 (1.4%)
3	3 (4.3%)	3 (4.1%)
>=4	9 (13.0%)	13 (17.6%)
p-value from Interaction Test[c]	0.9275	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	81 (83.5%)	71 (84.5%)
Censored	16 (16.5%)	13 (15.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.4, 2.8)	1.4 (0.7, 2.1)
50%	3.5 (2.8, 4.9)	3.4 (2.1, 7.1)
75%	13.2 (6.1, 27.9)	13.2 (9.7, 28.2)
Survival probability (95% CI) at		
Month 6	35.3% (25.9%, 44.8%)	40.2% (29.6%, 50.6%)
Month 12	26.7% (18.2%, 35.8%)	28.6% (19.2%, 38.7%)
Month 18	24.5% (16.3%, 33.5%)	20.8% (12.7%, 30.3%)
Month 24	21.0% (13.4%, 29.7%)	18.0% (10.4%, 27.3%)
Month 30	15.1% (8.7%, 23.3%)	13.9% (7.3%, 22.6%)
Month 36	11.4% (4.7%, 21.4%)	11.9% (5.7%, 20.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.90 (0.653, 1.244)	
p-value of 2-sided stratified log-rank test	0.5371	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	81	71
0	53 (65.4%)	50 (70.4%)
1	9 (11.1%)	7 (9.9%)
2	9 (11.1%)	4 (5.6%)
3	3 (3.7%)	1 (1.4%)
>=4	7 (8.6%)	9 (12.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	80 (84.2%)	94 (94.0%)
Censored	15 (15.8%)	6 (6.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 1.7)	1.1 (0.8, 2.0)
50%	2.8 (2.1, 3.6)	4.2 (2.2, 7.3)
75%	12.8 (5.8, 20.0)	13.2 (9.1, 17.3)
Survival probability (95% CI) at		
Month 6	33.7% (24.1%, 43.5%)	42.9% (33.0%, 52.4%)
Month 12	27.2% (18.3%, 36.9%)	26.2% (17.9%, 35.2%)
Month 18	18.1% (10.7%, 27.1%)	13.2% (7.3%, 20.8%)
Month 24	12.6% (6.4%, 20.9%)	11.0% (5.7%, 18.2%)
Month 30	11.2% (5.4%, 19.3%)	6.1% (2.3%, 12.4%)
Month 36	6.5% (2.3%, 13.9%)	3.7% (1.0%, 9.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.95 (0.700, 1.289)	
p-value of 2-sided stratified log-rank test	0.7615	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	80	94
0	50 (62.5%)	64 (68.1%)
1	9 (11.3%)	13 (13.8%)
2	9 (11.3%)	1 (1.1%)
3	3 (3.8%)	3 (3.2%)
>=4	9 (11.3%)	13 (13.8%)
p-value from Interaction Test[c]	0.8019	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	50 (51.5%)	40 (47.6%)
Censored	47 (48.5%)	44 (52.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.1)	1.4 (0.8, 2.3)
50%	10.2 (3.5, NE)	14.9 (2.8, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	55.3% (44.7%, 64.7%)	59.0% (47.2%, 69.0%)
Month 12	45.3% (34.4%, 55.5%)	54.0% (42.0%, 64.6%)
Month 18	43.8% (32.9%, 54.1%)	48.0% (35.6%, 59.3%)
Month 24	43.8% (32.9%, 54.1%)	48.0% (35.6%, 59.3%)
Month 30	43.8% (32.9%, 54.1%)	48.0% (35.6%, 59.3%)
Month 36	43.8% (32.9%, 54.1%)	41.4% (27.9%, 54.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.96 (0.629, 1.459)	
p-value of 2-sided stratified log-rank test	0.8312	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	50	40
0	28 (56.0%)	18 (45.0%)
1	8 (16.0%)	4 (10.0%)
2	2 (4.0%)	4 (10.0%)
3	3 (6.0%)	4 (10.0%)
>=4	9 (18.0%)	10 (25.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	39 (41.1%)	51 (51.0%)
Censored	56 (58.9%)	49 (49.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 3.5)	1.4 (0.9, 1.6)
50%	NE (6.6, NE)	5.6 (2.3, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	61.3% (50.0%, 70.8%)	49.6% (39.2%, 59.2%)
Month 12	55.6% (44.0%, 65.6%)	48.3% (37.8%, 58.0%)
Month 18	53.7% (42.0%, 64.0%)	48.3% (37.8%, 58.0%)
Month 24	51.6% (39.7%, 62.3%)	46.5% (35.9%, 56.4%)
Month 30	51.6% (39.7%, 62.3%)	44.2% (33.2%, 54.6%)
Month 36	51.6% (39.7%, 62.3%)	44.2% (33.2%, 54.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.18 (0.776, 1.800)	
p-value of 2-sided stratified log-rank test	0.4310	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	39	51
0	23 (59.0%)	26 (51.0%)
1	1 (2.6%)	6 (11.8%)
2	3 (7.7%)	7 (13.7%)
3	1 (2.6%)	5 (9.8%)
>=4	11 (28.2%)	7 (13.7%)
p-value from Interaction Test[c]	0.4286	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	61 (62.9%)	47 (56.0%)
Censored	36 (37.1%)	37 (44.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.3, 2.3)	2.1 (1.4, 2.8)
50%	3.7 (3.0, 12.1)	6.6 (2.8, 15.9)
75%	NE (24.0, NE)	NE (18.0, NE)
Survival probability (95% CI) at		
Month 6	43.1% (32.8%, 52.9%)	50.4% (38.6%, 61.0%)
Month 12	40.5% (30.4%, 50.4%)	44.0% (32.4%, 55.0%)
Month 18	37.3% (27.1%, 47.4%)	35.9% (24.3%, 47.6%)
Month 24	33.3% (23.1%, 43.9%)	33.3% (21.8%, 45.3%)
Month 30	31.1% (20.9%, 41.9%)	33.3% (21.8%, 45.3%)
Month 36	28.3% (17.9%, 39.6%)	33.3% (21.8%, 45.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.15 (0.781, 1.697)	
p-value of 2-sided stratified log-rank test	0.4743	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	61	47
0	28 (45.9%)	23 (48.9%)
1	15 (24.6%)	7 (14.9%)
2	3 (4.9%)	3 (6.4%)
3	2 (3.3%)	3 (6.4%)
>=4	13 (21.3%)	11 (23.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	72 (75.8%)	76 (76.0%)
Censored	23 (24.2%)	24 (24.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.8, 1.4)	1.4 (1.0, 2.1)
50%	1.7 (1.4, 2.2)	3.3 (2.5, 6.9)
75%	6.1 (2.8, 20.5)	17.3 (9.3, 27.7)
Survival probability (95% CI) at		
Month 6	26.1% (17.3%, 35.7%)	42.7% (32.5%, 52.4%)
Month 12	24.8% (16.1%, 34.4%)	31.2% (21.8%, 41.1%)
Month 18	15.2% (7.8%, 25.0%)	24.6% (15.6%, 34.6%)
Month 24	12.7% (5.7%, 22.6%)	19.3% (11.1%, 29.2%)
Month 30	12.7% (5.7%, 22.6%)	8.9% (3.2%, 18.3%)
Month 36	9.5% (3.3%, 19.9%)	5.9% (1.4%, 15.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.37 (0.984, 1.921)	
p-value of 2-sided stratified log-rank test	0.0610	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	72	76
0	31 (43.1%)	34 (44.7%)
1	15 (20.8%)	13 (17.1%)
2	4 (5.6%)	5 (6.6%)
3	9 (12.5%)	3 (3.9%)
>=4	13 (18.1%)	21 (27.6%)
p-value from Interaction Test[c]	0.3896	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	75 (77.3%)	67 (79.8%)
Censored	22 (22.7%)	17 (20.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.3, 2.3)	2.1 (1.4, 2.8)
50%	4.1 (3.0, 6.0)	4.3 (3.4, 11.0)
75%	26.3 (12.1, 34.1)	21.5 (14.4, 35.6)
Survival probability (95% CI) at		
Month 6	41.1% (31.1%, 50.7%)	46.9% (35.8%, 57.3%)
Month 12	35.5% (26.0%, 45.1%)	39.0% (28.3%, 49.5%)
Month 18	30.6% (21.5%, 40.2%)	26.4% (17.1%, 36.7%)
Month 24	25.0% (16.4%, 34.6%)	20.9% (12.5%, 30.7%)
Month 30	20.9% (12.9%, 30.2%)	16.7% (9.3%, 26.0%)
Month 36	15.5% (8.2%, 24.8%)	14.3% (7.2%, 23.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.04 (0.739, 1.450)	
p-value of 2-sided stratified log-rank test	0.8412	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	75	67
0	42 (56.0%)	43 (64.2%)
1	15 (20.0%)	7 (10.4%)
2	3 (4.0%)	3 (4.5%)
3	2 (2.7%)	3 (4.5%)
>=4	13 (17.3%)	11 (16.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	85 (89.5%)	93 (93.0%)
Censored	10 (10.5%)	7 (7.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.4 (1.0, 2.1)
50%	1.7 (1.4, 2.2)	3.4 (2.5, 6.9)
75%	6.1 (2.9, 17.1)	14.7 (9.3, 20.8)
Survival probability (95% CI) at		
Month 6	25.5% (17.1%, 34.8%)	42.9% (33.0%, 52.4%)
Month 12	21.9% (14.0%, 31.0%)	29.6% (20.9%, 38.8%)
Month 18	14.2% (7.8%, 22.5%)	19.1% (12.0%, 27.4%)
Month 24	7.8% (3.2%, 14.9%)	12.7% (7.0%, 20.2%)
Month 30	5.2% (1.7%, 11.6%)	5.8% (2.2%, 12.0%)
Month 36	3.9% (1.0%, 9.9%)	4.4% (1.3%, 10.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.33 (0.986, 1.803)	
p-value of 2-sided stratified log-rank test	0.0599	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	85	93
0	44 (51.8%)	51 (54.8%)
1	15 (17.6%)	13 (14.0%)
2	4 (4.7%)	5 (5.4%)
3	9 (10.6%)	3 (3.2%)
>=4	13 (15.3%)	21 (22.6%)
p-value from Interaction Test[c]	0.2054	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	40 (41.2%)	28 (33.3%)
Censored	57 (58.8%)	56 (66.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.0 (1.4, 8.7)	3.5 (0.9, 9.9)
50%	31.4 (14.6, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	69.9% (59.5%, 78.2%)	69.0% (57.3%, 78.0%)
Month 12	61.8% (50.6%, 71.1%)	64.4% (52.4%, 74.1%)
Month 18	60.3% (49.1%, 69.9%)	62.6% (50.4%, 72.6%)
Month 24	56.8% (45.2%, 66.9%)	62.6% (50.4%, 72.6%)
Month 30	54.7% (42.8%, 65.1%)	62.6% (50.4%, 72.6%)
Month 36	49.7% (37.1%, 61.1%)	62.6% (50.4%, 72.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.77 (0.471, 1.259)	
p-value of 2-sided stratified log-rank test	0.2959	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	40	28
0	20 (50.0%)	9 (32.1%)
1	7 (17.5%)	7 (25.0%)
2	3 (7.5%)	3 (10.7%)
3	4 (10.0%)	3 (10.7%)
>=4	6 (15.0%)	6 (21.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	30 (31.6%)	34 (34.0%)
Censored	65 (68.4%)	66 (66.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	4.4 (1.4, 16.8)	5.2 (1.4, 10.9)
50%	NE (24.2, NE)	NE (15.3, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	73.3% (62.5%, 81.4%)	71.1% (60.7%, 79.3%)
Month 12	67.5% (56.0%, 76.5%)	64.2% (53.0%, 73.3%)
Month 18	65.4% (53.6%, 74.9%)	60.9% (49.4%, 70.5%)
Month 24	63.1% (50.7%, 73.1%)	60.9% (49.4%, 70.5%)
Month 30	60.3% (47.3%, 71.1%)	60.9% (49.4%, 70.5%)
Month 36	60.3% (47.3%, 71.1%)	60.9% (49.4%, 70.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.95 (0.579, 1.566)	
p-value of 2-sided stratified log-rank test	0.8588	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	30	34
0	15 (50.0%)	15 (44.1%)
1	2 (6.7%)	5 (14.7%)
2	3 (10.0%)	4 (11.8%)
3	2 (6.7%)	3 (8.8%)
>=4	8 (26.7%)	7 (20.6%)
p-value from Interaction Test[c]	0.6040	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	68 (70.1%)	53 (63.1%)
Censored	29 (29.9%)	31 (36.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.9, 2.2)	1.5 (0.8, 2.1)
50%	3.4 (2.8, 4.3)	3.7 (2.2, 12.6)
75%	27.9 (8.1, NE)	31.9 (13.0, NE)
Survival probability (95% CI) at		
Month 6	35.7% (26.1%, 45.5%)	47.1% (35.6%, 57.8%)
Month 12	31.5% (22.1%, 41.3%)	40.3% (28.9%, 51.4%)
Month 18	31.5% (22.1%, 41.3%)	30.0% (19.1%, 41.8%)
Month 24	25.3% (16.0%, 35.7%)	25.0% (14.5%, 37.0%)
Month 30	23.0% (13.8%, 33.6%)	25.0% (14.5%, 37.0%)
Month 36	20.5% (11.4%, 31.3%)	21.9% (11.6%, 34.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.13 (0.780, 1.623)	
p-value of 2-sided stratified log-rank test	0.5265	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	68	53
0	30 (44.1%)	32 (60.4%)
1	15 (22.1%)	6 (11.3%)
2	4 (5.9%)	4 (7.5%)
3	7 (10.3%)	3 (5.7%)
>=4	12 (17.6%)	8 (15.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	77 (81.1%)	79 (79.0%)
Censored	18 (18.9%)	21 (21.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.4 (0.9, 1.4)
50%	2.0 (1.5, 2.3)	2.3 (1.7, 3.5)
75%	4.1 (2.8, 12.5)	10.0 (4.4, 21.7)
Survival probability (95% CI) at		
Month 6	21.6% (13.7%, 30.7%)	31.7% (22.6%, 41.2%)
Month 12	17.7% (10.4%, 26.5%)	21.7% (13.6%, 31.1%)
Month 18	11.5% (5.5%, 19.8%)	18.6% (10.9%, 27.9%)
Month 24	8.6% (3.1%, 17.6%)	14.0% (7.3%, 22.8%)
Month 30	8.6% (3.1%, 17.6%)	12.0% (5.7%, 20.8%)
Month 36	8.6% (3.1%, 17.6%)	9.6% (3.8%, 18.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.22 (0.887, 1.691)	
p-value of 2-sided stratified log-rank test	0.2111	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	77	79
0	29 (37.7%)	32 (40.5%)
1	17 (22.1%)	17 (21.5%)
2	3 (3.9%)	10 (12.7%)
3	5 (6.5%)	2 (2.5%)
>=4	23 (29.9%)	18 (22.8%)
p-value from Interaction Test[c]	0.5938	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	81 (83.5%)	70 (83.3%)
Censored	16 (16.5%)	14 (16.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.2 (0.9, 2.2)	1.5 (0.8, 2.1)
50%	3.4 (2.8, 4.3)	3.7 (2.2, 9.6)
75%	13.2 (5.3, 27.9)	16.7 (11.3, 22.8)
Survival probability (95% CI) at		
Month 6	33.8% (24.5%, 43.3%)	43.3% (32.4%, 53.7%)
Month 12	25.1% (16.9%, 34.2%)	35.2% (24.9%, 45.7%)
Month 18	22.8% (14.9%, 31.7%)	20.3% (12.2%, 30.0%)
Month 24	17.4% (10.3%, 26.1%)	14.9% (8.0%, 23.8%)
Month 30	14.8% (8.2%, 23.1%)	12.2% (6.0%, 20.7%)
Month 36	11.6% (5.7%, 19.8%)	10.7% (4.9%, 18.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.08 (0.778, 1.495)	
p-value of 2-sided stratified log-rank test	0.6510	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	81	70
0	43 (53.1%)	49 (70.0%)
1	15 (18.5%)	6 (8.6%)
2	4 (4.9%)	4 (5.7%)
3	7 (8.6%)	3 (4.3%)
>=4	12 (14.8%)	8 (11.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	86 (90.5%)	92 (92.0%)
Censored	9 (9.5%)	8 (8.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.1)	1.4 (0.9, 1.4)
50%	2.0 (1.5, 2.2)	2.6 (1.7, 3.5)
75%	3.9 (2.8, 12.5)	10.3 (4.7, 15.0)
Survival probability (95% CI) at		
Month 6	21.6% (13.9%, 30.5%)	32.7% (23.6%, 42.0%)
Month 12	16.9% (10.0%, 25.3%)	20.8% (13.3%, 29.4%)
Month 18	12.1% (6.3%, 19.8%)	14.2% (8.1%, 22.0%)
Month 24	5.4% (1.8%, 11.9%)	9.8% (4.9%, 16.9%)
Month 30	4.1% (1.1%, 10.2%)	7.7% (3.4%, 14.2%)
Month 36	4.1% (1.1%, 10.2%)	6.4% (2.5%, 12.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.23 (0.907, 1.664)	
p-value of 2-sided stratified log-rank test	0.1762	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	86	92
0	38 (44.2%)	45 (48.9%)
1	17 (19.8%)	17 (18.5%)
2	3 (3.5%)	10 (10.9%)
3	5 (5.8%)	2 (2.2%)
>=4	23 (26.7%)	18 (19.6%)
p-value from Interaction Test[c]	0.4321	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	45 (46.4%)	39 (46.4%)
Censored	52 (53.6%)	45 (53.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 2.1)	0.9 (0.8, 1.4)
50%	NE (3.0, NE)	13.3 (1.4, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	55.4% (44.8%, 64.8%)	55.6% (43.9%, 65.8%)
Month 12	52.6% (41.8%, 62.3%)	52.3% (40.5%, 62.8%)
Month 18	51.0% (40.2%, 60.9%)	48.6% (36.7%, 59.5%)
Month 24	51.0% (40.2%, 60.9%)	48.6% (36.7%, 59.5%)
Month 30	51.0% (40.2%, 60.9%)	48.6% (36.7%, 59.5%)
Month 36	51.0% (40.2%, 60.9%)	48.6% (36.7%, 59.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.09 (0.710, 1.689)	
p-value of 2-sided stratified log-rank test	0.7007	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	45	39
0	18 (40.0%)	17 (43.6%)
1	8 (17.8%)	5 (12.8%)
2	5 (11.1%)	0
3	1 (2.2%)	4 (10.3%)
>=4	13 (28.9%)	13 (33.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	34 (35.8%)	32 (32.0%)
Censored	61 (64.2%)	68 (68.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 3.4)	2.3 (1.0, 16.4)
50%	NE (11.4, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	64.2% (53.1%, 73.3%)	71.7% (61.4%, 79.6%)
Month 12	61.0% (49.5%, 70.6%)	67.4% (56.7%, 76.1%)
Month 18	61.0% (49.5%, 70.6%)	65.7% (54.6%, 74.7%)
Month 24	58.2% (46.0%, 68.6%)	63.3% (51.5%, 72.9%)
Month 30	58.2% (46.0%, 68.6%)	63.3% (51.5%, 72.9%)
Month 36	58.2% (46.0%, 68.6%)	63.3% (51.5%, 72.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.73 (0.446, 1.198)	
p-value of 2-sided stratified log-rank test	0.2149	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	34	32
0	16 (47.1%)	12 (37.5%)
1	7 (20.6%)	4 (12.5%)
2	2 (5.9%)	4 (12.5%)
3	1 (2.9%)	1 (3.1%)
>=4	8 (23.5%)	11 (34.4%)
p-value from Interaction Test[c]	0.3024	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	51 (52.6%)	47 (56.0%)
Censored	46 (47.4%)	37 (44.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.5 (2.1, 4.2)	2.2 (1.4, 3.9)
50%	13.9 (7.4, 29.5)	8.3 (5.0, 20.1)
75%	NE (NE, NE)	NE (22.3, NE)
Survival probability (95% CI) at		
Month 6	63.2% (52.4%, 72.1%)	58.1% (46.1%, 68.3%)
Month 12	52.1% (40.9%, 62.2%)	44.3% (32.5%, 55.5%)
Month 18	45.7% (34.4%, 56.4%)	39.1% (27.5%, 50.4%)
Month 24	42.1% (30.7%, 53.0%)	34.8% (23.4%, 46.5%)
Month 30	38.3% (27.0%, 49.5%)	34.8% (23.4%, 46.5%)
Month 36	36.4% (25.2%, 47.7%)	34.8% (23.4%, 46.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.82 (0.544, 1.230)	
p-value of 2-sided stratified log-rank test	0.3401	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	51	47
0	29 (56.9%)	28 (59.6%)
1	13 (25.5%)	9 (19.1%)
2	5 (9.8%)	4 (8.5%)
3	1 (2.0%)	2 (4.3%)
>=4	3 (5.9%)	4 (8.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	47 (49.5%)	53 (53.0%)
Censored	48 (50.5%)	47 (47.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.1 (2.1, 3.9)	2.1 (1.4, 3.3)
50%	11.5 (4.7, NE)	11.4 (4.7, 31.1)
75%	NE (37.5, NE)	NE (31.1, NE)
Survival probability (95% CI) at		
Month 6	57.9% (46.6%, 67.5%)	58.9% (48.3%, 68.0%)
Month 12	49.7% (38.5%, 60.0%)	48.0% (37.1%, 58.2%)
Month 18	44.3% (32.8%, 55.1%)	44.7% (33.7%, 55.1%)
Month 24	42.0% (30.4%, 53.2%)	42.5% (31.2%, 53.3%)
Month 30	42.0% (30.4%, 53.2%)	42.5% (31.2%, 53.3%)
Month 36	42.0% (30.4%, 53.2%)	32.3% (19.7%, 45.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.92 (0.620, 1.373)	
p-value of 2-sided stratified log-rank test	0.6839	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	47	53
0	30 (63.8%)	29 (54.7%)
1	10 (21.3%)	11 (20.8%)
2	3 (6.4%)	2 (3.8%)
3	3 (6.4%)	4 (7.5%)
>=4	1 (2.1%)	7 (13.2%)
p-value from Interaction Test[c]	0.7684	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	70 (72.2%)	64 (76.2%)
Censored	27 (27.8%)	20 (23.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.5 (2.1, 4.2)	2.2 (1.4, 3.7)
50%	9.5 (5.6, 13.2)	6.7 (4.4, 12.6)
75%	32.5 (19.5, NE)	21.5 (13.2, NE)
Survival probability (95% CI) at		
Month 6	58.7% (48.1%, 67.9%)	53.1% (41.7%, 63.3%)
Month 12	43.2% (33.0%, 53.0%)	40.3% (29.6%, 50.8%)
Month 18	35.1% (25.5%, 44.9%)	28.6% (19.1%, 38.8%)
Month 24	30.1% (20.9%, 39.8%)	23.3% (14.6%, 33.1%)
Month 30	26.3% (17.6%, 35.9%)	20.5% (12.3%, 30.1%)
Month 36	21.8% (13.6%, 31.3%)	20.5% (12.3%, 30.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.86 (0.606, 1.213)	
p-value of 2-sided stratified log-rank test	0.3929	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	70	64
0	48 (68.6%)	45 (70.3%)
1	13 (18.6%)	9 (14.1%)
2	5 (7.1%)	4 (6.3%)
3	1 (1.4%)	2 (3.1%)
>=4	3 (4.3%)	4 (6.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	69 (72.6%)	87 (87.0%)
Censored	26 (27.4%)	13 (13.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (2.0, 3.5)	2.1 (1.4, 3.3)
50%	8.4 (4.2, 16.2)	9.3 (4.7, 12.2)
75%	24.6 (19.2, NE)	22.1 (15.8, 31.3)
Survival probability (95% CI) at		
Month 6	55.7% (44.8%, 65.2%)	59.2% (48.8%, 68.2%)
Month 12	46.2% (35.6%, 56.2%)	40.8% (31.1%, 50.3%)
Month 18	36.4% (26.4%, 46.5%)	30.6% (21.8%, 39.8%)
Month 24	27.3% (18.2%, 37.2%)	23.1% (15.3%, 31.9%)
Month 30	23.2% (14.7%, 32.9%)	19.8% (12.5%, 28.3%)
Month 36	20.4% (12.4%, 29.9%)	12.2% (6.4%, 20.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

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Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.88 (0.639, 1.214)	
p-value of 2-sided stratified log-rank test	0.4356	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	69	87
0	52 (75.4%)	63 (72.4%)
1	10 (14.5%)	11 (12.6%)
2	3 (4.3%)	2 (2.3%)
3	3 (4.3%)	4 (4.6%)
>=4	1 (1.4%)	7 (8.0%)
p-value from Interaction Test[c]	0.8570	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	53 (54.6%)	41 (48.8%)
Censored	44 (45.4%)	43 (51.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.8)	1.4 (0.8, 2.1)
50%	8.4 (3.5, 31.9)	10.4 (2.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	56.3% (45.7%, 65.7%)	55.1% (43.3%, 65.3%)
Month 12	45.5% (34.7%, 55.6%)	48.6% (36.8%, 59.5%)
Month 18	45.5% (34.7%, 55.6%)	48.6% (36.8%, 59.5%)
Month 24	40.2% (29.2%, 50.8%)	45.8% (33.4%, 57.3%)
Month 30	40.2% (29.2%, 50.8%)	45.8% (33.4%, 57.3%)
Month 36	37.6% (26.5%, 48.7%)	41.6% (28.1%, 54.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.98 (0.649, 1.483)	
p-value of 2-sided stratified log-rank test	0.9056	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	53	41
0	24 (45.3%)	22 (53.7%)
1	9 (17.0%)	9 (22.0%)
2	9 (17.0%)	2 (4.9%)
3	2 (3.8%)	1 (2.4%)
>=4	9 (17.0%)	7 (17.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	45 (47.4%)	41 (41.0%)
Censored	50 (52.6%)	59 (59.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.1)	1.1 (0.8, 2.1)
50%	9.7 (3.3, NE)	NE (3.5, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	56.3% (45.1%, 66.0%)	58.1% (47.6%, 67.3%)
Month 12	49.9% (38.5%, 60.3%)	58.1% (47.6%, 67.3%)
Month 18	42.9% (30.8%, 54.5%)	56.5% (45.8%, 65.9%)
Month 24	42.9% (30.8%, 54.5%)	56.5% (45.8%, 65.9%)
Month 30	42.9% (30.8%, 54.5%)	56.5% (45.8%, 65.9%)
Month 36	42.9% (30.8%, 54.5%)	56.5% (45.8%, 65.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.83 (0.539, 1.273)	
p-value of 2-sided stratified log-rank test	0.3827	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	45	41
0	26 (57.8%)	19 (46.3%)
1	7 (15.6%)	8 (19.5%)
2	2 (4.4%)	2 (4.9%)
3	3 (6.7%)	3 (7.3%)
>=4	7 (15.6%)	9 (22.0%)
p-value from Interaction Test[c]	0.6417	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	66 (68.0%)	69 (82.1%)
Censored	31 (32.0%)	15 (17.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 1.7)	1.2 (0.7, 1.4)
50%	3.6 (2.6, 7.1)	2.1 (1.4, 2.6)
75%	28.4 (12.9, NE)	6.7 (3.7, 13.4)
Survival probability (95% CI) at		
Month 6	40.7% (30.6%, 50.6%)	25.8% (16.7%, 35.8%)
Month 12	36.0% (25.9%, 46.2%)	18.8% (10.9%, 28.3%)
Month 18	29.9% (19.8%, 40.7%)	14.1% (7.2%, 23.1%)
Month 24	27.8% (17.8%, 38.7%)	14.1% (7.2%, 23.1%)
Month 30	23.2% (13.5%, 34.3%)	12.1% (5.7%, 21.1%)
Month 36	15.9% (6.7%, 28.5%)	9.1% (3.2%, 18.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.64 (0.456, 0.910)	
p-value of 2-sided stratified log-rank test	0.0133	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	66	69
0	34 (51.5%)	38 (55.1%)
1	12 (18.2%)	11 (15.9%)
2	1 (1.5%)	3 (4.3%)
3	6 (9.1%)	5 (7.2%)
>=4	13 (19.7%)	12 (17.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	74 (77.9%)	73 (73.0%)
Censored	21 (22.1%)	27 (27.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 1.5)	1.4 (0.9, 1.5)
50%	2.8 (1.7, 4.2)	3.3 (2.1, 5.6)
75%	13.9 (5.5, 27.7)	17.7 (8.7, 28.4)
Survival probability (95% CI) at		
Month 6	31.3% (21.9%, 41.1%)	36.7% (27.0%, 46.4%)
Month 12	25.2% (16.6%, 34.7%)	32.8% (23.3%, 42.5%)
Month 18	20.7% (12.7%, 30.1%)	24.1% (15.1%, 34.2%)
Month 24	18.4% (10.5%, 28.1%)	24.1% (15.1%, 34.2%)
Month 30	11.5% (4.9%, 21.3%)	11.6% (4.5%, 22.3%)
Month 36	8.6% (2.8%, 18.6%)	11.6% (4.5%, 22.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.17 (0.840, 1.643)	
p-value of 2-sided stratified log-rank test	0.3509	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	74	73
0	37 (50.0%)	45 (61.6%)
1	17 (23.0%)	12 (16.4%)
2	9 (12.2%)	1 (1.4%)
3	3 (4.1%)	4 (5.5%)
>=4	8 (10.8%)	11 (15.1%)
p-value from Interaction Test[c]	0.0148	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	83 (85.6%)	74 (88.1%)
Censored	14 (14.4%)	10 (11.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 1.9)	1.0 (0.7, 1.4)
50%	3.6 (2.6, 5.3)	2.1 (1.4, 2.6)
75%	13.2 (7.1, 24.3)	6.7 (3.7, 13.4)
Survival probability (95% CI) at		
Month 6	36.9% (27.2%, 46.5%)	25.4% (16.6%, 35.2%)
Month 12	26.8% (18.2%, 36.1%)	19.0% (11.3%, 28.2%)
Month 18	20.8% (13.2%, 29.7%)	12.2% (6.1%, 20.5%)
Month 24	17.2% (10.2%, 25.7%)	12.2% (6.1%, 20.5%)
Month 30	12.3% (6.4%, 20.1%)	9.1% (4.0%, 17.0%)
Month 36	8.4% (3.4%, 16.4%)	6.9% (2.3%, 14.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.73 (0.531, 1.008)	
p-value of 2-sided stratified log-rank test	0.0605	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	83	74
0	51 (61.4%)	43 (58.1%)
1	12 (14.5%)	11 (14.9%)
2	1 (1.2%)	3 (4.1%)
3	6 (7.2%)	5 (6.8%)
>=4	13 (15.7%)	12 (16.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	86 (90.5%)	93 (93.0%)
Censored	9 (9.5%)	7 (7.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.1 (0.8, 1.4)	1.4 (0.9, 1.5)
50%	2.8 (1.6, 4.2)	3.4 (2.1, 5.8)
75%	13.9 (5.5, 20.1)	15.5 (8.8, 18.5)
Survival probability (95% CI) at		
Month 6	30.9% (21.7%, 40.5%)	36.7% (27.3%, 46.2%)
Month 12	25.2% (16.8%, 34.5%)	28.6% (20.0%, 37.7%)
Month 18	19.2% (11.8%, 28.0%)	18.4% (11.4%, 26.6%)
Month 24	13.2% (7.1%, 21.2%)	12.0% (6.5%, 19.3%)
Month 30	6.0% (2.2%, 12.4%)	5.4% (2.0%, 11.3%)
Month 36	4.5% (1.4%, 10.7%)	4.4% (1.4%, 9.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.10 (0.810, 1.488)	
p-value of 2-sided stratified log-rank test	0.5598	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	86	93
0	49 (57.0%)	65 (69.9%)
1	17 (19.8%)	12 (12.9%)
2	9 (10.5%)	1 (1.1%)
3	3 (3.5%)	4 (4.3%)
>=4	8 (9.3%)	11 (11.8%)
p-value from Interaction Test[c]	0.0638	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	36 (37.1%)	22 (26.2%)
Censored	61 (62.9%)	62 (73.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.0, 8.3)	3.7 (1.4, NE)
50%	NE (13.2, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	68.0% (57.5%, 76.5%)	74.4% (63.2%, 82.7%)
Month 12	62.5% (51.5%, 71.7%)	70.8% (58.9%, 79.8%)
Month 18	60.9% (49.8%, 70.3%)	70.8% (58.9%, 79.8%)
Month 24	60.9% (49.8%, 70.3%)	70.8% (58.9%, 79.8%)
Month 30	58.8% (47.2%, 68.6%)	70.8% (58.9%, 79.8%)
Month 36	58.8% (47.2%, 68.6%)	70.8% (58.9%, 79.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.70 (0.407, 1.202)	
p-value of 2-sided stratified log-rank test	0.1914	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	36	22
0	15 (41.7%)	9 (40.9%)
1	11 (30.6%)	7 (31.8%)
2	3 (8.3%)	1 (4.5%)
3	3 (8.3%)	3 (13.6%)
>=4	4 (11.1%)	2 (9.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	31 (32.6%)	40 (40.0%)
Censored	64 (67.4%)	60 (60.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.3 (0.9, 8.3)	2.1 (0.9, 4.2)
50%	NE (28.7, NE)	NE (13.9, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	67.5% (56.4%, 76.3%)	65.2% (54.6%, 73.8%)
Month 12	64.3% (52.9%, 73.6%)	61.3% (50.5%, 70.5%)
Month 18	64.3% (52.9%, 73.6%)	59.6% (48.6%, 69.0%)
Month 24	64.3% (52.9%, 73.6%)	57.6% (46.2%, 67.4%)
Month 30	61.1% (48.4%, 71.6%)	55.2% (43.3%, 65.5%)
Month 36	61.1% (48.4%, 71.6%)	52.3% (39.7%, 63.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.17 (0.728, 1.892)	
p-value of 2-sided stratified log-rank test	0.5043	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	31	40
0	15 (48.4%)	24 (60.0%)
1	10 (32.3%)	8 (20.0%)
2	3 (9.7%)	2 (5.0%)
3	2 (6.5%)	1 (2.5%)
>=4	1 (3.2%)	5 (12.5%)
p-value from Interaction Test[c]	0.1343	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	67 (69.1%)	49 (58.3%)
Censored	30 (30.9%)	35 (41.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.4 (0.8, 2.1)
50%	2.8 (1.7, 4.3)	3.7 (2.2, 13.4)
75%	27.9 (5.6, NE)	NE (17.0, NE)
Survival probability (95% CI) at		
Month 6	34.5% (24.9%, 44.3%)	48.8% (37.3%, 59.4%)
Month 12	30.2% (20.8%, 40.0%)	43.5% (32.0%, 54.5%)
Month 18	30.2% (20.8%, 40.0%)	35.8% (24.3%, 47.3%)
Month 24	27.8% (18.4%, 38.1%)	30.8% (19.5%, 42.9%)
Month 30	24.8% (15.0%, 35.8%)	30.8% (19.5%, 42.9%)
Month 36	NE (NE, NE)	30.8% (19.5%, 42.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.23 (0.847, 1.794)	
p-value of 2-sided stratified log-rank test	0.2706	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	67	49
0	35 (52.2%)	29 (59.2%)
1	7 (10.4%)	4 (8.2%)
2	6 (9.0%)	1 (2.0%)
3	5 (7.5%)	5 (10.2%)
>=4	14 (20.9%)	10 (20.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	72 (75.8%)	76 (76.0%)
Censored	23 (24.2%)	24 (24.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.1 (0.8, 1.4)
50%	2.8 (1.7, 3.5)	2.8 (1.9, 5.3)
75%	8.3 (4.4, 18.2)	16.1 (7.1, 27.7)
Survival probability (95% CI) at		
Month 6	25.1% (16.4%, 34.7%)	35.7% (26.2%, 45.4%)
Month 12	22.1% (13.8%, 31.7%)	28.7% (19.5%, 38.5%)
Month 18	17.2% (9.6%, 26.6%)	20.9% (12.7%, 30.6%)
Month 24	15.0% (7.8%, 24.5%)	19.0% (11.0%, 28.7%)
Month 30	12.5% (5.7%, 22.2%)	14.8% (7.4%, 24.6%)
Month 36	12.5% (5.7%, 22.2%)	9.9% (3.7%, 19.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.14 (0.813, 1.593)	
p-value of 2-sided stratified log-rank test	0.4455	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	72	76
0	42 (58.3%)	38 (50.0%)
1	10 (13.9%)	12 (15.8%)
2	6 (8.3%)	7 (9.2%)
3	5 (6.9%)	2 (2.6%)
>=4	9 (12.5%)	17 (22.4%)
p-value from Interaction Test[c]	0.6804	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	83 (85.6%)	69 (82.1%)
Censored	14 (14.4%)	15 (17.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.5)	1.4 (0.7, 2.1)
50%	2.8 (1.7, 4.3)	3.7 (2.2, 9.6)
75%	9.5 (5.0, 26.3)	17.0 (12.6, 28.2)
Survival probability (95% CI) at		
Month 6	31.0% (22.0%, 40.4%)	43.3% (32.4%, 53.7%)
Month 12	23.4% (15.5%, 32.4%)	36.7% (26.3%, 47.2%)
Month 18	21.1% (13.5%, 29.8%)	23.6% (14.9%, 33.5%)
Month 24	18.3% (11.1%, 26.9%)	18.1% (10.5%, 27.5%)
Month 30	12.7% (6.6%, 20.8%)	15.3% (8.3%, 24.3%)
Month 36	NE (NE, NE)	11.0% (4.8%, 20.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.18 (0.851, 1.642)	
p-value of 2-sided stratified log-rank test	0.3138	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	83	69
0	51 (61.4%)	49 (71.0%)
1	7 (8.4%)	4 (5.8%)
2	6 (7.2%)	1 (1.4%)
3	5 (6.0%)	5 (7.2%)
>=4	14 (16.9%)	10 (14.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	84 (88.4%)	93 (93.0%)
Censored	11 (11.6%)	7 (7.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.1 (0.8, 1.4)
50%	2.3 (1.7, 3.5)	2.8 (1.9, 4.7)
75%	6.2 (4.4, 15.4)	12.0 (7.8, 17.3)
Survival probability (95% CI) at		
Month 6	25.4% (17.0%, 34.8%)	35.7% (26.4%, 45.1%)
Month 12	19.4% (11.9%, 28.3%)	24.2% (16.2%, 33.0%)
Month 18	15.7% (8.9%, 24.1%)	15.8% (9.3%, 23.7%)
Month 24	9.2% (4.1%, 16.6%)	11.6% (6.2%, 18.8%)
Month 30	6.5% (2.5%, 13.4%)	8.1% (3.7%, 14.8%)
Month 36	6.5% (2.5%, 13.4%)	4.6% (1.5%, 10.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.13 (0.824, 1.545)	
p-value of 2-sided stratified log-rank test	0.4470	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	84	93
0	54 (64.3%)	55 (59.1%)
1	10 (11.9%)	12 (12.9%)
2	6 (7.1%)	7 (7.5%)
3	5 (6.0%)	2 (2.2%)
>=4	9 (10.7%)	17 (18.3%)
p-value from Interaction Test[c]	0.6424	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	38 (39.2%)	33 (39.3%)
Censored	59 (60.8%)	51 (60.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.9, 6.3)	1.4 (0.8, 2.3)
50%	NE (10.4, NE)	NE (3.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	67.0% (56.5%, 75.5%)	60.7% (49.0%, 70.5%)
Month 12	59.3% (48.3%, 68.7%)	57.8% (46.0%, 67.9%)
Month 18	57.7% (46.6%, 67.3%)	57.8% (46.0%, 67.9%)
Month 24	57.7% (46.6%, 67.3%)	57.8% (46.0%, 67.9%)
Month 30	57.7% (46.6%, 67.3%)	57.8% (46.0%, 67.9%)
Month 36	57.7% (46.6%, 67.3%)	57.8% (46.0%, 67.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.14 (0.715, 1.827)	
p-value of 2-sided stratified log-rank test	0.6128	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	38	33
0	18 (47.4%)	14 (42.4%)
1	3 (7.9%)	5 (15.2%)
2	4 (10.5%)	3 (9.1%)
3	2 (5.3%)	3 (9.1%)
>=4	11 (28.9%)	8 (24.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	39 (41.1%)	38 (38.0%)
Censored	56 (58.9%)	62 (62.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.1)	2.1 (1.4, 5.2)
50%	NE (3.0, NE)	NE (12.7, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	57.1% (45.9%, 66.8%)	65.0% (54.4%, 73.7%)
Month 12	55.7% (44.4%, 65.5%)	62.4% (51.7%, 71.5%)
Month 18	55.7% (44.4%, 65.5%)	59.1% (47.9%, 68.6%)
Month 24	53.4% (41.8%, 63.7%)	59.1% (47.9%, 68.6%)
Month 30	53.4% (41.8%, 63.7%)	56.0% (43.7%, 66.6%)
Month 36	53.4% (41.8%, 63.7%)	56.0% (43.7%, 66.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1302 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.83 (0.523, 1.304)	
p-value of 2-sided stratified log-rank test	0.4165	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	39	38
0	17 (43.6%)	17 (44.7%)
1	4 (10.3%)	5 (13.2%)
2	3 (7.7%)	3 (7.9%)
3	3 (7.7%)	1 (2.6%)
>=4	12 (30.8%)	12 (31.6%)
p-value from Interaction Test[c]	0.3382	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1302_c30_ttiw_age.sas, Output: t_2_1302_c30_ttiw_age.rtf, Generated on: 02SEP2024 13:58, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	68 (75.6%)	63 (72.4%)
Censored	22 (24.4%)	24 (27.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.7 (1.4, 2.2)	1.2 (0.7, 2.1)
50%	3.0 (2.6, 3.5)	3.7 (2.1, 6.1)
75%	23.1 (4.2, NE)	17.3 (9.9, 40.3)
Survival probability (95% CI) at		
Month 6	31.1% (21.7%, 40.9%)	40.4% (29.8%, 50.8%)
Month 12	29.7% (20.4%, 39.5%)	29.7% (19.4%, 40.7%)
Month 18	29.7% (20.4%, 39.5%)	20.2% (10.8%, 31.7%)
Month 24	21.7% (12.9%, 32.0%)	20.2% (10.8%, 31.7%)
Month 30	19.8% (11.2%, 30.1%)	17.7% (8.8%, 29.1%)
Month 36	15.2% (7.4%, 25.6%)	14.7% (6.4%, 26.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.02 (0.720, 1.435)	
p-value of 2-sided stratified log-rank test	0.9111	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	68	63
0	42 (61.8%)	38 (60.3%)
1	7 (10.3%)	7 (11.1%)
2	10 (14.7%)	3 (4.8%)
3	3 (4.4%)	2 (3.2%)
>=4	6 (8.8%)	13 (20.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	30 (85.7%)	26 (78.8%)
Censored	5 (14.3%)	7 (21.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.4)	0.9 (0.7, 2.1)
50%	2.1 (1.4, 2.8)	3.1 (1.1, 5.8)
75%	4.6 (2.3, 35.9)	12.8 (4.2, 31.3)
Survival probability (95% CI) at		
Month 6	24.4% (11.6%, 39.6%)	32.1% (16.4%, 49.1%)
Month 12	21.3% (9.5%, 36.3%)	25.0% (11.2%, 41.6%)
Month 18	17.8% (7.0%, 32.5%)	21.4% (8.8%, 37.7%)
Month 24	14.2% (4.8%, 28.5%)	17.9% (6.6%, 33.6%)
Month 30	14.2% (4.8%, 28.5%)	13.4% (3.8%, 28.9%)
Month 36	9.5% (2.1%, 23.9%)	8.9% (1.7%, 23.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.06 (0.617, 1.815)	
p-value of 2-sided stratified log-rank test	0.8222	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	30	26
0	16 (53.3%)	13 (50.0%)
1	4 (13.3%)	7 (26.9%)
2	2 (6.7%)	2 (7.7%)
3	2 (6.7%)	2 (7.7%)
>=4	6 (20.0%)	2 (7.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	39 (58.2%)	40 (62.5%)
Censored	28 (41.8%)	24 (37.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (0.9, 3.4)	1.4 (0.8, 2.1)
50%	6.5 (3.6, 12.1)	7.1 (2.3, 9.7)
75%	27.9 (12.1, NE)	27.7 (9.7, NE)
Survival probability (95% CI) at		
Month 6	50.9% (37.4%, 62.8%)	51.7% (38.3%, 63.5%)
Month 12	39.2% (25.9%, 52.2%)	32.2% (20.0%, 45.1%)
Month 18	31.4% (18.7%, 44.8%)	32.2% (20.0%, 45.1%)
Month 24	31.4% (18.7%, 44.8%)	28.2% (15.8%, 41.9%)
Month 30	23.5% (11.4%, 38.0%)	22.5% (10.0%, 38.1%)
Month 36	23.5% (11.4%, 38.0%)	22.5% (10.0%, 38.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.83 (0.535, 1.296)	
p-value of 2-sided stratified log-rank test	0.4179	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	39	40
0	21 (53.8%)	27 (67.5%)
1	7 (17.9%)	6 (15.0%)
2	6 (15.4%)	0
3	1 (2.6%)	0
>=4	4 (10.3%)	7 (17.5%)
p-value from Interaction Test[c]	0.6808	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	76 (84.4%)	79 (90.8%)
Censored	14 (15.6%)	8 (9.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.7 (1.4, 2.2)	1.2 (0.7, 2.1)
50%	3.0 (2.6, 3.5)	3.6 (2.1, 6.1)
75%	17.4 (4.2, 24.3)	13.2 (8.3, 17.3)
Survival probability (95% CI) at		
Month 6	30.7% (21.4%, 40.5%)	40.7% (30.3%, 50.8%)
Month 12	26.9% (18.0%, 36.5%)	28.4% (19.3%, 38.3%)
Month 18	24.2% (15.7%, 33.7%)	13.1% (6.8%, 21.4%)
Month 24	17.5% (10.1%, 26.5%)	11.8% (5.9%, 19.9%)
Month 30	14.8% (8.0%, 23.5%)	9.2% (4.1%, 16.8%)
Month 36	9.8% (4.2%, 18.1%)	7.9% (3.2%, 15.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.94 (0.680, 1.285)	
p-value of 2-sided stratified log-rank test	0.6984	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	76	79
0	50 (65.8%)	54 (68.4%)
1	7 (9.2%)	7 (8.9%)
2	10 (13.2%)	3 (3.8%)
3	3 (3.9%)	2 (2.5%)
>=4	6 (7.9%)	13 (16.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	31 (88.6%)	28 (84.8%)
Censored	4 (11.4%)	5 (15.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.4)	0.9 (0.7, 2.1)
50%	2.1 (1.4, 2.8)	3.1 (1.1, 5.8)
75%	4.6 (2.3, 35.9)	10.9 (3.8, 31.3)
Survival probability (95% CI) at		
Month 6	24.4% (11.6%, 39.6%)	30.0% (15.0%, 46.6%)
Month 12	21.3% (9.5%, 36.3%)	23.3% (10.3%, 39.4%)
Month 18	15.2% (5.6%, 29.3%)	20.0% (8.1%, 35.6%)
Month 24	12.2% (3.9%, 25.6%)	16.7% (6.1%, 31.8%)
Month 30	12.2% (3.9%, 25.6%)	13.3% (4.2%, 27.8%)
Month 36	8.1% (1.7%, 21.3%)	10.0% (2.5%, 23.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.03 (0.613, 1.747)	
p-value of 2-sided stratified log-rank test	0.8792	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	31	28
0	17 (54.8%)	15 (53.6%)
1	4 (12.9%)	7 (25.0%)
2	2 (6.5%)	2 (7.1%)
3	2 (6.5%)	2 (7.1%)
>=4	6 (19.4%)	2 (7.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	54 (80.6%)	58 (90.6%)
Censored	13 (19.4%)	6 (9.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.5 (0.9, 3.4)	1.4 (0.8, 2.1)
50%	5.0 (3.4, 9.6)	4.6 (2.3, 9.4)
75%	13.2 (9.9, 26.3)	13.2 (9.6, 24.6)
Survival probability (95% CI) at		
Month 6	45.1% (32.6%, 56.7%)	48.4% (35.8%, 60.0%)
Month 12	30.1% (19.3%, 41.7%)	27.5% (17.1%, 38.8%)
Month 18	21.8% (12.5%, 32.7%)	19.4% (10.7%, 30.0%)
Month 24	19.8% (10.9%, 30.7%)	15.9% (8.1%, 26.0%)
Month 30	11.9% (5.0%, 21.9%)	8.1% (2.8%, 17.1%)
Month 36	11.9% (5.0%, 21.9%)	4.0% (0.5%, 14.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.84 (0.578, 1.215)	
p-value of 2-sided stratified log-rank test	0.3508	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	54	58
0	36 (66.7%)	45 (77.6%)
1	7 (13.0%)	6 (10.3%)
2	6 (11.1%)	0
3	1 (1.9%)	0
>=4	4 (7.4%)	7 (12.1%)
p-value from Interaction Test[c]	0.6816	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	46 (51.1%)	41 (47.1%)
Censored	44 (48.9%)	46 (52.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.9, 2.1)	1.4 (0.8, 1.7)
50%	9.9 (3.5, NE)	31.8 (2.2, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	56.9% (45.6%, 66.6%)	54.4% (43.1%, 64.4%)
Month 12	43.8% (32.3%, 54.8%)	54.4% (43.1%, 64.4%)
Month 18	42.0% (30.5%, 53.1%)	52.3% (40.7%, 62.7%)
Month 24	42.0% (30.5%, 53.1%)	52.3% (40.7%, 62.7%)
Month 30	42.0% (30.5%, 53.1%)	52.3% (40.7%, 62.7%)
Month 36	42.0% (30.5%, 53.1%)	42.3% (26.9%, 56.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.95 (0.624, 1.450)	
p-value of 2-sided stratified log-rank test	0.8097	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	46	41
0	30 (65.2%)	20 (48.8%)
1	5 (10.9%)	5 (12.2%)
2	3 (6.5%)	5 (12.2%)
3	1 (2.2%)	5 (12.2%)
>=4	7 (15.2%)	6 (14.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	14 (40.0%)	12 (36.4%)
Censored	21 (60.0%)	21 (63.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.3 (0.9, 18.8)	2.8 (0.7, 19.3)
50%	NE (5.8, NE)	NE (2.8, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	67.5% (49.0%, 80.6%)	65.8% (45.7%, 79.9%)
Month 12	60.9% (42.2%, 75.2%)	65.8% (45.7%, 79.9%)
Month 18	60.9% (42.2%, 75.2%)	61.4% (40.9%, 76.6%)
Month 24	56.6% (37.4%, 71.9%)	57.0% (36.5%, 73.1%)
Month 30	56.6% (37.4%, 71.9%)	57.0% (36.5%, 73.1%)
Month 36	56.6% (37.4%, 71.9%)	57.0% (36.5%, 73.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.03 (0.467, 2.271)	
p-value of 2-sided stratified log-rank test	0.9487	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	14	12
0	7 (50.0%)	7 (58.3%)
1	2 (14.3%)	0
2	1 (7.1%)	2 (16.7%)
3	0	0
>=4	4 (28.6%)	3 (25.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	29 (43.3%)	38 (59.4%)
Censored	38 (56.7%)	26 (40.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.1 (0.7, 2.6)	1.4 (0.8, 1.6)
50%	NE (3.0, NE)	3.5 (1.6, 13.0)
75%	NE (NE, NE)	NE (13.0, NE)
Survival probability (95% CI) at		
Month 6	54.6% (41.1%, 66.3%)	47.5% (34.6%, 59.4%)
Month 12	52.4% (38.8%, 64.4%)	39.7% (27.1%, 52.0%)
Month 18	50.1% (36.3%, 62.3%)	37.2% (24.7%, 49.7%)
Month 24	50.1% (36.3%, 62.3%)	37.2% (24.7%, 49.7%)
Month 30	50.1% (36.3%, 62.3%)	33.8% (21.1%, 47.0%)
Month 36	50.1% (36.3%, 62.3%)	33.8% (21.1%, 47.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.30 (0.801, 2.109)	
p-value of 2-sided stratified log-rank test	0.2749	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	29	38
0	14 (48.3%)	17 (44.7%)
1	2 (6.9%)	5 (13.2%)
2	1 (3.4%)	4 (10.5%)
3	3 (10.3%)	4 (10.5%)
>=4	9 (31.0%)	8 (21.1%)
p-value from Interaction Test[c]	0.5808	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	65 (72.2%)	61 (70.1%)
Censored	25 (27.8%)	26 (29.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 1.5)	1.8 (1.2, 2.1)
50%	2.3 (1.5, 3.5)	3.5 (2.2, 6.6)
75%	20.5 (4.1, NE)	20.8 (11.8, 33.9)
Survival probability (95% CI) at		
Month 6	30.6% (21.1%, 40.6%)	42.4% (31.6%, 52.7%)
Month 12	30.6% (21.1%, 40.6%)	34.1% (23.5%, 45.0%)
Month 18	26.7% (17.4%, 37.0%)	27.1% (16.7%, 38.6%)
Month 24	22.3% (13.2%, 32.9%)	24.4% (14.1%, 36.2%)
Month 30	22.3% (13.2%, 32.9%)	15.2% (6.5%, 27.5%)
Month 36	16.2% (7.6%, 27.7%)	11.4% (3.7%, 24.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.17 (0.826, 1.667)	
p-value of 2-sided stratified log-rank test	0.3673	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	65	61
0	31 (47.7%)	26 (42.6%)
1	14 (21.5%)	8 (13.1%)
2	5 (7.7%)	3 (4.9%)
3	6 (9.2%)	5 (8.2%)
>=4	9 (13.8%)	19 (31.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	28 (80.0%)	22 (66.7%)
Censored	7 (20.0%)	11 (33.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.7, 1.4)	2.1 (1.1, 2.9)
50%	1.7 (1.3, 2.2)	4.3 (2.1, 22.4)
75%	6.0 (2.2, NE)	28.5 (5.6, NE)
Survival probability (95% CI) at		
Month 6	25.7% (12.8%, 40.8%)	40.3% (22.5%, 57.5%)
Month 12	22.9% (10.8%, 37.6%)	36.7% (19.6%, 54.0%)
Month 18	19.0% (7.9%, 33.8%)	33.0% (16.8%, 50.3%)
Month 24	19.0% (7.9%, 33.8%)	25.7% (11.4%, 42.6%)
Month 30	19.0% (7.9%, 33.8%)	21.4% (8.4%, 38.2%)
Month 36	19.0% (7.9%, 33.8%)	21.4% (8.4%, 38.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.60 (0.901, 2.859)	
p-value of 2-sided stratified log-rank test	0.1079	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	28	22
0	13 (46.4%)	7 (31.8%)
1	4 (14.3%)	9 (40.9%)
2	0	1 (4.5%)
3	3 (10.7%)	1 (4.5%)
>=4	8 (28.6%)	4 (18.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	40 (59.7%)	40 (62.5%)
Censored	27 (40.3%)	24 (37.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.2 (0.8, 3.4)	2.1 (0.9, 2.8)
50%	5.6 (3.5, 15.3)	7.1 (3.1, 15.5)
75%	27.9 (15.3, NE)	27.7 (15.5, NE)
Survival probability (95% CI) at		
Month 6	45.9% (32.7%, 58.1%)	54.7% (41.2%, 66.3%)
Month 12	41.9% (29.0%, 54.3%)	41.0% (28.1%, 53.5%)
Month 18	30.4% (17.8%, 44.1%)	30.7% (18.3%, 43.9%)
Month 24	26.6% (14.2%, 40.8%)	27.3% (15.1%, 40.9%)
Month 30	22.2% (10.2%, 37.1%)	22.7% (10.8%, 37.3%)
Month 36	22.2% (10.2%, 37.1%)	22.7% (10.8%, 37.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.03 (0.662, 1.603)	
p-value of 2-sided stratified log-rank test	0.8902	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	40	40
0	15 (37.5%)	24 (60.0%)
1	12 (30.0%)	3 (7.5%)
2	2 (5.0%)	4 (10.0%)
3	2 (5.0%)	0
>=4	9 (22.5%)	9 (22.5%)
p-value from Interaction Test[c]	0.3948	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	76 (84.4%)	77 (88.5%)
Censored	14 (15.6%)	10 (11.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 1.5)	1.8 (1.2, 2.1)
50%	2.3 (1.6, 3.0)	3.6 (2.4, 6.9)
75%	17.4 (4.1, 29.0)	15.7 (10.0, 21.5)
Survival probability (95% CI) at		
Month 6	30.3% (21.0%, 40.1%)	43.0% (32.4%, 53.1%)
Month 12	27.8% (18.8%, 37.5%)	33.0% (23.2%, 43.1%)
Month 18	23.6% (15.1%, 33.2%)	20.7% (12.6%, 30.3%)
Month 24	16.2% (9.0%, 25.3%)	13.8% (7.2%, 22.5%)
Month 30	14.8% (7.9%, 23.7%)	8.3% (3.4%, 15.9%)
Month 36	7.9% (2.9%, 16.1%)	6.6% (2.4%, 14.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.09 (0.790, 1.499)	
p-value of 2-sided stratified log-rank test	0.6012	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	76	77
0	42 (55.3%)	42 (54.5%)
1	14 (18.4%)	8 (10.4%)
2	5 (6.6%)	3 (3.9%)
3	6 (7.9%)	5 (6.5%)
>=4	9 (11.8%)	19 (24.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	30 (85.7%)	24 (72.7%)
Censored	5 (14.3%)	9 (27.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.7, 1.4)	2.1 (1.1, 2.9)
50%	1.7 (1.3, 2.2)	3.9 (2.1, 14.7)
75%	6.0 (2.2, NE)	22.8 (4.6, NE)
Survival probability (95% CI) at		
Month 6	25.7% (12.8%, 40.8%)	38.0% (20.9%, 54.9%)
Month 12	22.9% (10.8%, 37.6%)	34.5% (18.2%, 51.5%)
Month 18	19.6% (8.4%, 34.2%)	31.1% (15.6%, 47.9%)
Month 24	16.3% (6.3%, 30.5%)	24.2% (10.7%, 40.6%)
Month 30	13.1% (4.3%, 26.8%)	20.7% (8.4%, 36.7%)
Month 36	13.1% (4.3%, 26.8%)	20.7% (8.4%, 36.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.60 (0.917, 2.778)	
p-value of 2-sided stratified log-rank test	0.0971	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	30	24
0	15 (50.0%)	9 (37.5%)
1	4 (13.3%)	9 (37.5%)
2	0	1 (4.2%)
3	3 (10.0%)	1 (4.2%)
>=4	8 (26.7%)	4 (16.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	54 (80.6%)	59 (92.2%)
Censored	13 (19.4%)	5 (7.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.8, 3.4)	1.9 (0.8, 2.8)
50%	4.9 (3.4, 6.5)	5.4 (2.8, 11.0)
75%	15.4 (6.8, 26.3)	16.0 (11.2, 24.6)
Survival probability (95% CI) at		
Month 6	41.9% (29.7%, 53.6%)	50.0% (37.3%, 61.5%)
Month 12	33.8% (22.4%, 45.4%)	34.4% (23.1%, 45.9%)
Month 18	22.8% (13.1%, 34.1%)	20.3% (11.5%, 30.9%)
Month 24	16.6% (8.2%, 27.5%)	15.6% (8.0%, 25.5%)
Month 30	10.4% (4.0%, 20.3%)	8.8% (3.4%, 17.5%)
Month 36	10.4% (4.0%, 20.3%)	4.4% (0.5%, 15.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.00 (0.686, 1.444)	
p-value of 2-sided stratified log-rank test	0.9833	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	54	59
0	29 (53.7%)	43 (72.9%)
1	12 (22.2%)	3 (5.1%)
2	2 (3.7%)	4 (6.8%)
3	2 (3.7%)	0
>=4	9 (16.7%)	9 (15.3%)
p-value from Interaction Test[c]	0.2563	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	32 (35.6%)	29 (33.3%)
Censored	58 (64.4%)	58 (66.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	6.6 (1.4, 14.6)	5.8 (1.2, 14.1)
50%	NE (22.5, NE)	NE (15.3, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	75.6% (65.1%, 83.4%)	73.8% (62.9%, 81.9%)
Month 12	66.7% (55.1%, 76.0%)	66.1% (54.3%, 75.5%)
Month 18	63.1% (51.0%, 73.0%)	62.2% (49.9%, 72.3%)
Month 24	60.9% (48.5%, 71.2%)	62.2% (49.9%, 72.3%)
Month 30	55.8% (42.4%, 67.2%)	62.2% (49.9%, 72.3%)
Month 36	55.8% (42.4%, 67.2%)	62.2% (49.9%, 72.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.92 (0.555, 1.520)	
p-value of 2-sided stratified log-rank test	0.7521	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	32	29
0	15 (46.9%)	14 (48.3%)
1	5 (15.6%)	4 (13.8%)
2	4 (12.5%)	3 (10.3%)
3	3 (9.4%)	3 (10.3%)
>=4	5 (15.6%)	5 (17.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	9 (25.7%)	8 (24.2%)
Censored	26 (74.3%)	25 (75.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	19.1 (4.2, NE)	9.9 (0.8, NE)
50%	NE (31.4, NE)	NE (9.9, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	85.1% (67.8%, 93.5%)	75.3% (54.9%, 87.5%)
Month 12	78.4% (59.8%, 89.1%)	70.9% (49.8%, 84.4%)
Month 18	78.4% (59.8%, 89.1%)	70.9% (49.8%, 84.4%)
Month 24	74.0% (54.2%, 86.3%)	70.9% (49.8%, 84.4%)
Month 30	74.0% (54.2%, 86.3%)	70.9% (49.8%, 84.4%)
Month 36	66.6% (43.0%, 82.3%)	70.9% (49.8%, 84.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.29 (0.497, 3.352)	
p-value of 2-sided stratified log-rank test	0.6027	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	9	8
0	6 (66.7%)	2 (25.0%)
1	2 (22.2%)	2 (25.0%)
2	0	1 (12.5%)
3	0	1 (12.5%)
>=4	1 (11.1%)	2 (25.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	29 (43.3%)	25 (39.1%)
Censored	38 (56.7%)	39 (60.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 3.0)	4.2 (1.0, 5.8)
50%	19.5 (3.7, NE)	NE (5.8, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	58.1% (44.5%, 69.5%)	62.8% (49.1%, 73.8%)
Month 12	53.3% (39.4%, 65.4%)	59.0% (45.2%, 70.4%)
Month 18	53.3% (39.4%, 65.4%)	56.4% (42.3%, 68.3%)
Month 24	49.8% (35.2%, 62.8%)	56.4% (42.3%, 68.3%)
Month 30	49.8% (35.2%, 62.8%)	56.4% (42.3%, 68.3%)
Month 36	45.6% (30.3%, 59.7%)	56.4% (42.3%, 68.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.75 (0.436, 1.273)	
p-value of 2-sided stratified log-rank test	0.2825	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	29	25
0	14 (48.3%)	8 (32.0%)
1	2 (6.9%)	6 (24.0%)
2	2 (6.9%)	3 (12.0%)
3	3 (10.3%)	2 (8.0%)
>=4	8 (27.6%)	6 (24.0%)
p-value from Interaction Test[c]	0.7412	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	73 (81.1%)	66 (75.9%)
Censored	17 (18.9%)	21 (24.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.4 (0.8, 1.5)
50%	2.2 (1.6, 3.1)	2.9 (1.9, 4.2)
75%	10.2 (4.1, 20.5)	12.9 (6.7, 27.9)
Survival probability (95% CI) at		
Month 6	28.2% (19.2%, 38.0%)	35.2% (25.1%, 45.5%)
Month 12	22.6% (14.2%, 32.2%)	26.2% (16.6%, 36.8%)
Month 18	18.1% (10.5%, 27.4%)	18.4% (9.9%, 28.9%)
Month 24	10.9% (4.8%, 19.7%)	16.3% (8.3%, 26.7%)
Month 30	10.9% (4.8%, 19.7%)	14.0% (6.5%, 24.4%)
Month 36	10.9% (4.8%, 19.7%)	11.2% (4.4%, 21.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.13 (0.809, 1.579)	
p-value of 2-sided stratified log-rank test	0.4694	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	73	66
0	26 (35.6%)	32 (48.5%)
1	16 (21.9%)	9 (13.6%)
2	3 (4.1%)	7 (10.6%)
3	5 (6.8%)	3 (4.5%)
>=4	23 (31.5%)	15 (22.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	29 (82.9%)	24 (72.7%)
Censored	6 (17.1%)	9 (27.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.1)	0.9 (0.7, 1.4)
50%	2.1 (0.9, 2.8)	1.5 (1.0, 3.1)
75%	4.2 (2.2, NE)	4.6 (2.1, NE)
Survival probability (95% CI) at		
Month 6	20.0% (8.8%, 34.4%)	24.3% (10.8%, 40.8%)
Month 12	20.0% (8.8%, 34.4%)	20.8% (8.5%, 36.9%)
Month 18	16.0% (5.9%, 30.5%)	20.8% (8.5%, 36.9%)
Month 24	16.0% (5.9%, 30.5%)	17.4% (6.3%, 32.9%)
Month 30	16.0% (5.9%, 30.5%)	17.4% (6.3%, 32.9%)
Month 36	16.0% (5.9%, 30.5%)	17.4% (6.3%, 32.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.04 (0.593, 1.806)	
p-value of 2-sided stratified log-rank test	0.8896	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	29	24
0	13 (44.8%)	11 (45.8%)
1	5 (17.2%)	3 (12.5%)
2	2 (6.9%)	5 (20.8%)
3	4 (13.8%)	0
>=4	5 (17.2%)	5 (20.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	43 (64.2%)	42 (65.6%)
Censored	24 (35.8%)	22 (34.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 2.3)	2.1 (0.9, 2.3)
50%	3.4 (2.3, 4.4)	5.5 (2.8, 12.6)
75%	30.9 (5.8, NE)	20.7 (12.6, NE)
Survival probability (95% CI) at		
Month 6	35.2% (23.3%, 47.3%)	49.9% (36.7%, 61.8%)
Month 12	30.7% (19.2%, 43.0%)	39.2% (26.3%, 51.9%)
Month 18	30.7% (19.2%, 43.0%)	30.7% (18.2%, 44.2%)
Month 24	30.7% (19.2%, 43.0%)	20.5% (9.4%, 34.5%)
Month 30	25.6% (13.3%, 39.8%)	20.5% (9.4%, 34.5%)
Month 36	20.5% (8.6%, 35.9%)	16.4% (6.3%, 30.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.17 (0.759, 1.792)	
p-value of 2-sided stratified log-rank test	0.4843	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	43	42
0	20 (46.5%)	21 (50.0%)
1	11 (25.6%)	11 (26.2%)
2	2 (4.7%)	2 (4.8%)
3	3 (7.0%)	2 (4.8%)
>=4	7 (16.3%)	6 (14.3%)
p-value from Interaction Test[c]	0.9856	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	80 (88.9%)	78 (89.7%)
Censored	10 (11.1%)	9 (10.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.5)	1.4 (0.8, 1.6)
50%	2.2 (1.6, 3.1)	3.0 (1.9, 4.2)
75%	9.6 (4.1, 19.2)	12.0 (6.7, 17.3)
Survival probability (95% CI) at		
Month 6	28.6% (19.6%, 38.2%)	34.9% (25.0%, 44.9%)
Month 12	21.4% (13.4%, 30.5%)	24.6% (16.0%, 34.3%)
Month 18	17.6% (10.4%, 26.4%)	14.3% (7.7%, 22.8%)
Month 24	9.5% (4.3%, 17.1%)	10.4% (4.9%, 18.2%)
Month 30	8.1% (3.4%, 15.5%)	7.8% (3.2%, 15.0%)
Month 36	6.8% (2.6%, 13.8%)	6.2% (2.2%, 13.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.07 (0.785, 1.469)	
p-value of 2-sided stratified log-rank test	0.6576	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	80	78
0	33 (41.3%)	44 (56.4%)
1	16 (20.0%)	9 (11.5%)
2	3 (3.8%)	7 (9.0%)
3	5 (6.3%)	3 (3.8%)
>=4	23 (28.8%)	15 (19.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	32 (91.4%)	26 (78.8%)
Censored	3 (8.6%)	7 (21.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.1)	0.9 (0.7, 1.4)
50%	2.1 (0.9, 2.8)	1.5 (1.0, 3.1)
75%	4.2 (2.2, 20.3)	4.6 (2.1, 39.1)
Survival probability (95% CI) at		
Month 6	20.0% (8.8%, 34.4%)	24.3% (10.8%, 40.8%)
Month 12	20.0% (8.8%, 34.4%)	20.8% (8.5%, 36.9%)
Month 18	14.3% (5.2%, 27.7%)	20.8% (8.5%, 36.9%)
Month 24	8.6% (2.2%, 20.6%)	17.4% (6.3%, 32.9%)
Month 30	8.6% (2.2%, 20.6%)	17.4% (6.3%, 32.9%)
Month 36	8.6% (2.2%, 20.6%)	17.4% (6.3%, 32.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.11 (0.650, 1.895)	
p-value of 2-sided stratified log-rank test	0.6874	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	32	26
0	16 (50.0%)	13 (50.0%)
1	5 (15.6%)	3 (11.5%)
2	2 (6.3%)	5 (19.2%)
3	4 (12.5%)	0
>=4	5 (15.6%)	5 (19.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	55 (82.1%)	58 (90.6%)
Censored	12 (17.9%)	6 (9.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.3 (0.8, 2.2)	2.1 (0.9, 2.3)
50%	3.2 (2.3, 4.4)	4.6 (2.8, 9.1)
75%	8.1 (4.9, 27.9)	16.1 (10.3, 21.7)
Survival probability (95% CI) at		
Month 6	31.0% (20.1%, 42.5%)	46.9% (34.3%, 58.4%)
Month 12	20.9% (11.8%, 31.7%)	33.6% (22.3%, 45.3%)
Month 18	19.1% (10.4%, 29.8%)	18.5% (9.9%, 29.1%)
Month 24	17.0% (8.7%, 27.6%)	11.8% (5.2%, 21.2%)
Month 30	12.1% (5.0%, 22.6%)	8.4% (3.1%, 17.1%)
Month 36	9.7% (3.5%, 19.9%)	6.7% (2.2%, 14.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.15 (0.793, 1.670)	
p-value of 2-sided stratified log-rank test	0.4606	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	55	58
0	32 (58.2%)	37 (63.8%)
1	11 (20.0%)	11 (19.0%)
2	2 (3.6%)	2 (3.4%)
3	3 (5.5%)	2 (3.4%)
>=4	7 (12.7%)	6 (10.3%)
p-value from Interaction Test[c]	0.9611	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	37 (41.1%)	28 (32.2%)
Censored	53 (58.9%)	59 (67.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 3.4)	2.8 (0.9, 23.2)
50%	NE (7.2, NE)	NE (23.2, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	61.5% (50.3%, 70.9%)	73.9% (63.1%, 82.0%)
Month 12	56.7% (45.1%, 66.7%)	67.5% (55.7%, 76.7%)
Month 18	54.9% (43.1%, 65.2%)	65.5% (53.4%, 75.1%)
Month 24	54.9% (43.1%, 65.2%)	62.4% (49.2%, 73.0%)
Month 30	54.9% (43.1%, 65.2%)	62.4% (49.2%, 73.0%)
Month 36	54.9% (43.1%, 65.2%)	62.4% (49.2%, 73.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.74 (0.453, 1.211)	
p-value of 2-sided stratified log-rank test	0.2329	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	37	28
0	22 (59.5%)	12 (42.9%)
1	4 (10.8%)	3 (10.7%)
2	1 (2.7%)	2 (7.1%)
3	1 (2.7%)	4 (14.3%)
>=4	9 (24.3%)	7 (25.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	10 (28.6%)	10 (30.3%)
Censored	25 (71.4%)	23 (69.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	4.1 (0.9, NE)	5.2 (0.7, NE)
50%	NE (NE, NE)	NE (12.7, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	73.7% (55.4%, 85.4%)	72.4% (52.1%, 85.2%)
Month 12	70.5% (52.0%, 82.9%)	72.4% (52.1%, 85.2%)
Month 18	70.5% (52.0%, 82.9%)	63.3% (42.0%, 78.6%)
Month 24	70.5% (52.0%, 82.9%)	63.3% (42.0%, 78.6%)
Month 30	70.5% (52.0%, 82.9%)	63.3% (42.0%, 78.6%)
Month 36	70.5% (52.0%, 82.9%)	63.3% (42.0%, 78.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.22 (0.494, 2.998)	
p-value of 2-sided stratified log-rank test	0.6884	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	10	10
0	3 (30.0%)	5 (50.0%)
1	2 (20.0%)	1 (10.0%)
2	3 (30.0%)	0
3	0	1 (10.0%)
>=4	2 (20.0%)	3 (30.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	32 (47.8%)	33 (51.6%)
Censored	35 (52.2%)	31 (48.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.0 (0.8, 1.4)
50%	3.0 (1.4, NE)	3.5 (1.4, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	48.9% (35.9%, 60.7%)	47.8% (34.8%, 59.6%)
Month 12	48.9% (35.9%, 60.7%)	45.5% (32.5%, 57.6%)
Month 18	48.9% (35.9%, 60.7%)	45.5% (32.5%, 57.6%)
Month 24	44.5% (30.1%, 57.8%)	45.5% (32.5%, 57.6%)
Month 30	44.5% (30.1%, 57.8%)	45.5% (32.5%, 57.6%)
Month 36	44.5% (30.1%, 57.8%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.98 (0.598, 1.596)	
p-value of 2-sided stratified log-rank test	0.9178	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	32	33
0	9 (28.1%)	12 (36.4%)
1	9 (28.1%)	5 (15.2%)
2	3 (9.4%)	2 (6.1%)
3	1 (3.1%)	0
>=4	10 (31.3%)	14 (42.4%)
p-value from Interaction Test[c]	0.5258	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	43 (47.8%)	50 (57.5%)
Censored	47 (52.2%)	37 (42.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.5 (2.1, 4.2)	2.2 (1.4, 3.3)
50%	16.9 (5.6, NE)	7.2 (4.2, 13.0)
75%	NE (NE, NE)	NE (13.4, NE)
Survival probability (95% CI) at		
Month 6	60.8% (49.5%, 70.3%)	53.8% (42.3%, 63.9%)
Month 12	54.9% (43.3%, 65.1%)	40.7% (29.2%, 51.8%)
Month 18	49.9% (38.2%, 60.6%)	35.1% (23.9%, 46.6%)
Month 24	46.1% (34.2%, 57.2%)	32.4% (21.1%, 44.2%)
Month 30	46.1% (34.2%, 57.2%)	32.4% (21.1%, 44.2%)
Month 36	43.8% (31.8%, 55.2%)	32.4% (21.1%, 44.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.71 (0.469, 1.064)	
p-value of 2-sided stratified log-rank test	0.0938	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	43	50
0	24 (55.8%)	29 (58.0%)
1	10 (23.3%)	7 (14.0%)
2	5 (11.6%)	5 (10.0%)
3	1 (2.3%)	2 (4.0%)
>=4	3 (7.0%)	7 (14.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	19 (54.3%)	14 (42.4%)
Censored	16 (45.7%)	19 (57.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (0.7, 6.1)	2.2 (1.4, 20.1)
50%	8.4 (3.5, NE)	31.3 (3.1, NE)
75%	NE (21.7, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	61.4% (42.9%, 75.5%)	61.2% (40.9%, 76.4%)
Month 12	47.9% (30.0%, 63.8%)	61.2% (40.9%, 76.4%)
Month 18	47.9% (30.0%, 63.8%)	61.2% (40.9%, 76.4%)
Month 24	42.6% (24.3%, 59.7%)	53.1% (32.9%, 69.6%)
Month 30	42.6% (24.3%, 59.7%)	53.1% (32.9%, 69.6%)
Month 36	42.6% (24.3%, 59.7%)	47.8% (27.6%, 65.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.39 (0.671, 2.872)	
p-value of 2-sided stratified log-rank test	0.3700	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	19	14
0	12 (63.2%)	8 (57.1%)
1	4 (21.1%)	5 (35.7%)
2	0	0
3	3 (15.8%)	1 (7.1%)
>=4	0	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	36 (53.7%)	36 (56.3%)
Censored	31 (46.3%)	28 (43.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.1 (2.1, 4.3)	2.1 (0.8, 5.6)
50%	10.5 (4.3, 16.2)	8.3 (6.1, 31.1)
75%	NE (15.4, NE)	38.9 (30.7, NE)
Survival probability (95% CI) at		
Month 6	59.9% (46.3%, 71.0%)	63.6% (50.1%, 74.4%)
Month 12	47.1% (33.4%, 59.7%)	46.4% (33.0%, 58.8%)
Month 18	35.4% (21.7%, 49.4%)	40.7% (27.0%, 53.9%)
Month 24	35.4% (21.7%, 49.4%)	40.7% (27.0%, 53.9%)
Month 30	27.9% (14.6%, 42.8%)	40.7% (27.0%, 53.9%)
Month 36	27.9% (14.6%, 42.8%)	29.1% (13.9%, 46.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.95 (0.597, 1.508)	
p-value of 2-sided stratified log-rank test	0.8437	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	36	36
0	23 (63.9%)	20 (55.6%)
1	9 (25.0%)	8 (22.2%)
2	3 (8.3%)	1 (2.8%)
3	0	3 (8.3%)
>=4	1 (2.8%)	4 (11.1%)
p-value from Interaction Test[c]	0.2820	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	61 (67.8%)	73 (83.9%)
Censored	29 (32.2%)	14 (16.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.5 (2.1, 4.0)	2.2 (1.4, 3.4)
50%	11.5 (5.6, 19.6)	7.2 (4.2, 12.0)
75%	34.1 (24.6, NE)	18.4 (13.0, 27.0)
Survival probability (95% CI) at		
Month 6	58.8% (47.7%, 68.3%)	53.5% (42.4%, 63.3%)
Month 12	48.7% (37.7%, 58.9%)	39.0% (28.7%, 49.2%)
Month 18	43.5% (32.7%, 53.8%)	25.6% (16.8%, 35.3%)
Month 24	35.4% (25.1%, 45.8%)	18.0% (10.6%, 27.0%)
Month 30	32.5% (22.5%, 42.9%)	14.2% (7.6%, 22.7%)
Month 36	24.5% (15.3%, 34.9%)	12.1% (5.9%, 20.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.67 (0.477, 0.947)	
p-value of 2-sided stratified log-rank test	0.0222	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	61	73
0	42 (68.9%)	52 (71.2%)
1	10 (16.4%)	7 (9.6%)
2	5 (8.2%)	5 (6.8%)
3	1 (1.6%)	2 (2.7%)
>=4	3 (4.9%)	7 (9.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	24 (68.6%)	21 (63.6%)
Censored	11 (31.4%)	12 (36.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (0.7, 6.1)	2.2 (1.4, 3.9)
50%	7.6 (3.5, 21.7)	20.1 (3.1, 36.1)
75%	37.5 (13.2, NE)	36.6 (31.3, NE)
Survival probability (95% CI) at		
Month 6	61.4% (42.9%, 75.5%)	55.2% (35.7%, 71.1%)
Month 12	46.1% (28.7%, 61.8%)	51.8% (32.6%, 68.0%)
Month 18	39.9% (23.5%, 55.9%)	51.8% (32.6%, 68.0%)
Month 24	29.0% (14.4%, 45.4%)	44.9% (26.6%, 61.6%)
Month 30	29.0% (14.4%, 45.4%)	44.9% (26.6%, 61.6%)
Month 36	29.0% (14.4%, 45.4%)	37.4% (20.3%, 54.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.18 (0.642, 2.155)	
p-value of 2-sided stratified log-rank test	0.5950	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	24	21
0	17 (70.8%)	15 (71.4%)
1	4 (16.7%)	5 (23.8%)
2	0	0
3	3 (12.5%)	1 (4.8%)
>=4	0	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	54 (80.6%)	57 (89.1%)
Censored	13 (19.4%)	7 (10.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.7 (1.7, 4.2)	2.1 (0.8, 4.7)
50%	7.4 (4.2, 12.3)	7.5 (4.7, 11.2)
75%	16.2 (12.7, 29.5)	18.4 (12.2, 30.7)
Survival probability (95% CI) at		
Month 6	53.1% (40.2%, 64.4%)	60.9% (47.9%, 71.7%)
Month 12	38.7% (26.8%, 50.4%)	37.5% (25.8%, 49.1%)
Month 18	23.6% (13.8%, 34.8%)	25.0% (15.2%, 36.0%)
Month 24	19.9% (11.0%, 30.8%)	19.8% (11.0%, 30.5%)
Month 30	12.7% (5.7%, 22.6%)	16.0% (8.1%, 26.4%)
Month 36	12.7% (5.7%, 22.6%)	10.0% (3.9%, 19.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.97 (0.666, 1.404)	
p-value of 2-sided stratified log-rank test	0.8760	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	54	57
0	41 (75.9%)	41 (71.9%)
1	9 (16.7%)	8 (14.0%)
2	3 (5.6%)	1 (1.8%)
3	0	3 (5.3%)
>=4	1 (1.9%)	4 (7.0%)
p-value from Interaction Test[c]	0.2263	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	49 (54.4%)	43 (49.4%)
Censored	41 (45.6%)	44 (50.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 2.0)	1.0 (0.8, 1.5)
50%	9.7 (2.8, 23.1)	21.7 (2.1, NE)
75%	NE (23.1, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	55.9% (44.8%, 65.7%)	52.5% (41.3%, 62.5%)
Month 12	47.5% (36.0%, 58.2%)	50.9% (39.7%, 61.1%)
Month 18	43.5% (31.7%, 54.6%)	50.9% (39.7%, 61.1%)
Month 24	36.5% (24.5%, 48.4%)	48.5% (36.9%, 59.2%)
Month 30	36.5% (24.5%, 48.4%)	48.5% (36.9%, 59.2%)
Month 36	33.7% (21.7%, 46.0%)	44.5% (31.4%, 56.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.90 (0.599, 1.364)	
p-value of 2-sided stratified log-rank test	0.6242	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	49	43
0	26 (53.1%)	22 (51.2%)
1	9 (18.4%)	8 (18.6%)
2	7 (14.3%)	2 (4.7%)
3	2 (4.1%)	3 (7.0%)
>=4	5 (10.2%)	8 (18.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	19 (54.3%)	15 (45.5%)
Censored	16 (45.7%)	18 (54.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.3 (0.8, 3.4)	1.7 (0.7, 2.8)
50%	8.5 (2.3, NE)	8.3 (2.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	56.6% (38.7%, 71.2%)	51.1% (31.5%, 67.6%)
Month 12	47.5% (30.2%, 63.0%)	46.8% (27.6%, 64.0%)
Month 18	43.6% (26.4%, 59.6%)	46.8% (27.6%, 64.0%)
Month 24	43.6% (26.4%, 59.6%)	46.8% (27.6%, 64.0%)
Month 30	43.6% (26.4%, 59.6%)	46.8% (27.6%, 64.0%)
Month 36	43.6% (26.4%, 59.6%)	46.8% (27.6%, 64.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.12 (0.568, 2.205)	
p-value of 2-sided stratified log-rank test	0.7688	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	19	15
0	9 (47.4%)	6 (40.0%)
1	2 (10.5%)	3 (20.0%)
2	1 (5.3%)	1 (6.7%)
3	1 (5.3%)	1 (6.7%)
>=4	6 (31.6%)	4 (26.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	30 (44.8%)	24 (37.5%)
Censored	37 (55.2%)	40 (62.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 3.0)	1.5 (0.8, 7.0)
50%	8.4 (3.3, NE)	NE (7.0, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	56.3% (42.7%, 67.9%)	65.4% (51.9%, 75.9%)
Month 12	47.5% (33.7%, 60.0%)	61.2% (47.4%, 72.4%)
Month 18	47.5% (33.7%, 60.0%)	58.1% (43.7%, 70.1%)
Month 24	47.5% (33.7%, 60.0%)	58.1% (43.7%, 70.1%)
Month 30	47.5% (33.7%, 60.0%)	58.1% (43.7%, 70.1%)
Month 36	47.5% (33.7%, 60.0%)	58.1% (43.7%, 70.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.75 (0.438, 1.285)	
p-value of 2-sided stratified log-rank test	0.2909	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	30	24
0	15 (50.0%)	13 (54.2%)
1	5 (16.7%)	6 (25.0%)
2	3 (10.0%)	1 (4.2%)
3	2 (6.7%)	0
>=4	5 (16.7%)	4 (16.7%)
p-value from Interaction Test[c]	0.8138	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	72 (80.0%)	68 (78.2%)
Censored	18 (20.0%)	19 (21.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.8, 1.4)	1.3 (0.8, 1.5)
50%	2.2 (1.5, 3.6)	2.9 (2.1, 5.6)
75%	13.9 (4.2, 29.3)	15.5 (5.9, 26.2)
Survival probability (95% CI) at		
Month 6	30.2% (20.8%, 40.1%)	34.4% (24.3%, 44.7%)
Month 12	27.0% (17.9%, 37.0%)	26.8% (17.4%, 37.1%)
Month 18	21.9% (13.3%, 31.9%)	17.2% (9.0%, 27.5%)
Month 24	19.9% (11.5%, 30.0%)	17.2% (9.0%, 27.5%)
Month 30	13.3% (6.1%, 23.3%)	6.9% (1.5%, 18.1%)
Month 36	5.5% (0.7%, 18.7%)	6.9% (1.5%, 18.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.05 (0.750, 1.473)	
p-value of 2-sided stratified log-rank test	0.7948	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	72	68
0	40 (55.6%)	38 (55.9%)
1	12 (16.7%)	15 (22.1%)
2	6 (8.3%)	3 (4.4%)
3	4 (5.6%)	3 (4.4%)
>=4	10 (13.9%)	9 (13.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	25 (71.4%)	24 (72.7%)
Censored	10 (28.6%)	9 (27.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 2.1)	0.8 (0.7, 1.0)
50%	3.1 (1.4, 11.3)	1.8 (0.8, 3.3)
75%	32.9 (6.7, NE)	17.4 (2.1, NE)
Survival probability (95% CI) at		
Month 6	41.6% (25.1%, 57.3%)	26.7% (12.6%, 43.0%)
Month 12	31.7% (16.8%, 47.7%)	26.7% (12.6%, 43.0%)
Month 18	27.7% (13.5%, 43.9%)	23.3% (10.3%, 39.4%)
Month 24	27.7% (13.5%, 43.9%)	23.3% (10.3%, 39.4%)
Month 30	27.7% (13.5%, 43.9%)	20.0% (8.1%, 35.6%)
Month 36	22.2% (8.8%, 39.3%)	20.0% (8.1%, 35.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.72 (0.408, 1.273)	
p-value of 2-sided stratified log-rank test	0.2819	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	25	24
0	11 (44.0%)	16 (66.7%)
1	6 (24.0%)	4 (16.7%)
2	1 (4.0%)	0
3	1 (4.0%)	0
>=4	6 (24.0%)	4 (16.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	43 (64.2%)	50 (78.1%)
Censored	24 (35.8%)	14 (21.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.0 (0.9, 3.3)	1.4 (0.8, 1.7)
50%	4.4 (3.5, 10.2)	2.6 (2.1, 4.1)
75%	23.3 (10.2, NE)	11.3 (4.2, 29.3)
Survival probability (95% CI) at		
Month 6	41.1% (28.4%, 53.3%)	30.2% (19.1%, 42.0%)
Month 12	34.7% (22.5%, 47.2%)	24.1% (13.9%, 35.9%)
Month 18	28.1% (15.9%, 41.5%)	19.3% (9.9%, 31.0%)
Month 24	23.4% (11.3%, 38.0%)	19.3% (9.9%, 31.0%)
Month 30	11.7% (2.6%, 28.4%)	11.6% (3.7%, 24.3%)
Month 36	11.7% (2.6%, 28.4%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.73 (0.484, 1.106)	
p-value of 2-sided stratified log-rank test	0.1408	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	43	50
0	20 (46.5%)	29 (58.0%)
1	11 (25.6%)	4 (8.0%)
2	3 (7.0%)	1 (2.0%)
3	4 (9.3%)	6 (12.0%)
>=4	5 (11.6%)	10 (20.0%)
p-value from Interaction Test[c]	0.3425	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	82 (91.1%)	81 (93.1%)
Censored	8 (8.9%)	6 (6.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.3 (0.8, 1.5)
50%	2.2 (1.5, 3.6)	3.0 (2.1, 5.6)
75%	11.3 (4.2, 20.1)	12.0 (5.9, 17.3)
Survival probability (95% CI) at		
Month 6	29.6% (20.5%, 39.4%)	34.7% (24.8%, 44.7%)
Month 12	23.3% (15.0%, 32.7%)	24.9% (16.3%, 34.5%)
Month 18	18.1% (10.7%, 27.1%)	13.7% (7.3%, 22.0%)
Month 24	14.3% (7.7%, 22.7%)	8.4% (3.6%, 15.8%)
Month 30	7.8% (3.2%, 15.0%)	2.8% (0.5%, 8.6%)
Month 36	3.2% (0.4%, 11.8%)	2.8% (0.5%, 8.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.98 (0.718, 1.346)	
p-value of 2-sided stratified log-rank test	0.8926	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	82	81
0	50 (61.0%)	51 (63.0%)
1	12 (14.6%)	15 (18.5%)
2	6 (7.3%)	3 (3.7%)
3	4 (4.9%)	3 (3.7%)
>=4	10 (12.2%)	9 (11.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	27 (77.1%)	25 (75.8%)
Censored	8 (22.9%)	8 (24.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 2.1)	0.8 (0.7, 1.0)
50%	3.1 (1.4, 11.3)	1.8 (0.8, 3.3)
75%	16.5 (6.7, NE)	17.4 (2.1, NE)
Survival probability (95% CI) at		
Month 6	41.6% (25.1%, 57.3%)	26.7% (12.6%, 43.0%)
Month 12	32.7% (17.9%, 48.4%)	26.7% (12.6%, 43.0%)
Month 18	22.9% (10.4%, 38.2%)	23.3% (10.3%, 39.4%)
Month 24	22.9% (10.4%, 38.2%)	23.3% (10.3%, 39.4%)
Month 30	22.9% (10.4%, 38.2%)	20.0% (8.1%, 35.6%)
Month 36	18.3% (6.9%, 34.0%)	16.7% (6.1%, 31.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.75 (0.432, 1.304)	
p-value of 2-sided stratified log-rank test	0.3359	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	27	25
0	13 (48.1%)	17 (68.0%)
1	6 (22.2%)	4 (16.0%)
2	1 (3.7%)	0
3	1 (3.7%)	0
>=4	6 (22.2%)	4 (16.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	60 (89.6%)	61 (95.3%)
Censored	7 (10.4%)	3 (4.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (0.9, 3.1)	1.4 (0.8, 1.7)
50%	4.3 (3.3, 5.6)	2.7 (2.1, 4.1)
75%	13.2 (5.8, 23.2)	10.7 (4.2, 15.8)
Survival probability (95% CI) at		
Month 6	35.9% (24.4%, 47.5%)	29.7% (19.1%, 41.1%)
Month 12	26.3% (16.2%, 37.5%)	21.9% (12.7%, 32.6%)
Month 18	21.1% (12.0%, 31.9%)	14.1% (6.9%, 23.7%)
Month 24	12.3% (5.5%, 22.0%)	10.5% (4.5%, 19.6%)
Month 30	3.5% (0.7%, 10.7%)	5.3% (1.4%, 13.0%)
Month 36	3.5% (0.7%, 10.7%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.88 (0.611, 1.257)	
p-value of 2-sided stratified log-rank test	0.4820	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	60	61
0	37 (61.7%)	40 (65.6%)
1	11 (18.3%)	4 (6.6%)
2	3 (5.0%)	1 (1.6%)
3	4 (6.7%)	6 (9.8%)
>=4	5 (8.3%)	10 (16.4%)
p-value from Interaction Test[c]	0.7523	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	32 (35.6%)	36 (41.4%)
Censored	58 (64.4%)	51 (58.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.9, 8.3)	1.5 (0.8, 2.8)
50%	NE (13.2, NE)	NE (6.9, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	68.8% (57.8%, 77.4%)	61.8% (50.5%, 71.3%)
Month 12	62.6% (51.0%, 72.2%)	58.6% (47.1%, 68.5%)
Month 18	60.8% (49.0%, 70.7%)	58.6% (47.1%, 68.5%)
Month 24	60.8% (49.0%, 70.7%)	58.6% (47.1%, 68.5%)
Month 30	60.8% (49.0%, 70.7%)	55.8% (43.5%, 66.5%)
Month 36	60.8% (49.0%, 70.7%)	52.7% (39.6%, 64.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.21 (0.749, 1.945)	
p-value of 2-sided stratified log-rank test	0.4357	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	32	36
0	17 (53.1%)	22 (61.1%)
1	10 (31.3%)	9 (25.0%)
2	3 (9.4%)	0
3	0	1 (2.8%)
>=4	2 (6.3%)	4 (11.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	12 (34.3%)	12 (36.4%)
Censored	23 (65.7%)	21 (63.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	5.4 (1.5, NE)	1.7 (0.7, 13.9)
50%	NE (24.9, NE)	NE (4.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	73.4% (55.1%, 85.2%)	68.7% (48.2%, 82.4%)
Month 12	70.2% (51.6%, 82.8%)	60.3% (39.5%, 75.9%)
Month 18	70.2% (51.6%, 82.8%)	56.0% (35.3%, 72.4%)
Month 24	70.2% (51.6%, 82.8%)	56.0% (35.3%, 72.4%)
Month 30	59.6% (38.3%, 75.6%)	56.0% (35.3%, 72.4%)
Month 36	59.6% (38.3%, 75.6%)	56.0% (35.3%, 72.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.31 (0.576, 2.970)	
p-value of 2-sided stratified log-rank test	0.5219	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	12	12
0	4 (33.3%)	5 (41.7%)
1	5 (41.7%)	1 (8.3%)
2	1 (8.3%)	2 (16.7%)
3	2 (16.7%)	2 (16.7%)
>=4	0	2 (16.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	23 (34.3%)	14 (21.9%)
Censored	44 (65.7%)	50 (78.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.9, 4.2)	22.1 (2.1, NE)
50%	NE (4.2, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	63.2% (49.6%, 74.1%)	79.8% (67.1%, 88.0%)
Month 12	60.6% (46.6%, 72.0%)	77.5% (64.2%, 86.3%)
Month 18	60.6% (46.6%, 72.0%)	77.5% (64.2%, 86.3%)
Month 24	60.6% (46.6%, 72.0%)	73.6% (58.3%, 84.0%)
Month 30	60.6% (46.6%, 72.0%)	73.6% (58.3%, 84.0%)
Month 36	60.6% (46.6%, 72.0%)	73.6% (58.3%, 84.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.52 (0.269, 1.019)	
p-value of 2-sided stratified log-rank test	0.0527	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	23	14
0	9 (39.1%)	6 (42.9%)
1	6 (26.1%)	5 (35.7%)
2	2 (8.7%)	1 (7.1%)
3	3 (13.0%)	1 (7.1%)
>=4	3 (13.0%)	1 (7.1%)
p-value from Interaction Test[c]	0.1055	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	67 (74.4%)	66 (75.9%)
Censored	23 (25.6%)	21 (24.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.4 (0.8, 1.5)
50%	2.7 (1.5, 3.5)	2.8 (2.1, 5.7)
75%	13.9 (4.3, NE)	13.0 (8.6, 26.2)
Survival probability (95% CI) at		
Month 6	27.9% (18.8%, 37.7%)	39.6% (29.2%, 49.9%)
Month 12	26.3% (17.4%, 36.2%)	27.4% (17.5%, 38.1%)
Month 18	24.7% (15.9%, 34.5%)	17.4% (9.0%, 28.0%)
Month 24	20.6% (12.1%, 30.7%)	14.9% (7.0%, 25.6%)
Month 30	20.6% (12.1%, 30.7%)	12.4% (5.2%, 23.0%)
Month 36	18.0% (9.7%, 28.4%)	9.9% (3.6%, 20.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.02 (0.726, 1.443)	
p-value of 2-sided stratified log-rank test	0.9011	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	67	66
0	38 (56.7%)	35 (53.0%)
1	7 (10.4%)	8 (12.1%)
2	6 (9.0%)	5 (7.6%)
3	5 (7.5%)	5 (7.6%)
>=4	11 (16.4%)	13 (19.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	31 (88.6%)	21 (63.6%)
Censored	4 (11.4%)	12 (36.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.0)	0.9 (0.7, 2.1)
50%	1.6 (0.9, 2.8)	2.4 (1.1, 21.3)
75%	4.6 (2.8, 12.8)	31.3 (3.5, NE)
Survival probability (95% CI) at		
Month 6	20.0% (8.8%, 34.4%)	33.2% (16.8%, 50.7%)
Month 12	13.3% (4.5%, 27.0%)	33.2% (16.8%, 50.7%)
Month 18	8.9% (1.9%, 22.7%)	33.2% (16.8%, 50.7%)
Month 24	8.9% (1.9%, 22.7%)	29.1% (13.6%, 46.5%)
Month 30	8.9% (1.9%, 22.7%)	29.1% (13.6%, 46.5%)
Month 36	NE (NE, NE)	24.2% (9.9%, 41.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.61 (0.901, 2.866)	
p-value of 2-sided stratified log-rank test	0.0980	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	31	21
0	18 (58.1%)	11 (52.4%)
1	5 (16.1%)	3 (14.3%)
2	1 (3.2%)	2 (9.5%)
3	2 (6.5%)	0
>=4	5 (16.1%)	5 (23.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	41 (61.2%)	38 (59.4%)
Censored	26 (38.8%)	26 (40.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.6 (0.8, 2.3)	1.2 (0.8, 2.1)
50%	3.8 (2.4, 8.3)	4.6 (2.2, 17.5)
75%	28.1 (8.3, NE)	NE (17.5, NE)
Survival probability (95% CI) at		
Month 6	38.5% (25.9%, 51.0%)	48.0% (34.7%, 60.0%)
Month 12	33.7% (21.3%, 46.5%)	45.8% (32.6%, 58.0%)
Month 18	30.3% (18.0%, 43.6%)	35.7% (22.7%, 48.9%)
Month 24	30.3% (18.0%, 43.6%)	32.7% (19.9%, 46.2%)
Month 30	20.2% (8.2%, 35.9%)	28.1% (15.0%, 42.7%)
Month 36	20.2% (8.2%, 35.9%)	28.1% (15.0%, 42.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.09 (0.695, 1.704)	
p-value of 2-sided stratified log-rank test	0.7199	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	41	38
0	21 (51.2%)	21 (55.3%)
1	5 (12.2%)	5 (13.2%)
2	5 (12.2%)	1 (2.6%)
3	3 (7.3%)	2 (5.3%)
>=4	7 (17.1%)	9 (23.7%)
p-value from Interaction Test[c]	0.2722	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	80 (88.9%)	81 (93.1%)
Censored	10 (11.1%)	6 (6.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.4 (0.8, 1.5)
50%	2.7 (1.5, 3.5)	2.8 (2.1, 5.7)
75%	8.0 (4.3, 20.1)	12.6 (8.8, 16.1)
Survival probability (95% CI) at		
Month 6	27.7% (18.8%, 37.3%)	39.5% (29.2%, 49.6%)
Month 12	21.9% (13.9%, 31.0%)	25.9% (17.1%, 35.6%)
Month 18	20.7% (12.9%, 29.7%)	12.4% (6.4%, 20.4%)
Month 24	14.2% (7.8%, 22.6%)	7.4% (3.0%, 14.4%)
Month 30	11.6% (5.9%, 19.6%)	6.2% (2.3%, 12.8%)
Month 36	8.9% (3.9%, 16.4%)	4.9% (1.6%, 11.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.98 (0.711, 1.345)	
p-value of 2-sided stratified log-rank test	0.8873	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	80	81
0	51 (63.8%)	50 (61.7%)
1	7 (8.8%)	8 (9.9%)
2	6 (7.5%)	5 (6.2%)
3	5 (6.3%)	5 (6.2%)
>=4	11 (13.8%)	13 (16.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	33 (94.3%)	24 (72.7%)
Censored	2 (5.7%)	9 (27.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.8 (0.7, 1.0)	0.9 (0.7, 2.1)
50%	1.6 (0.9, 2.8)	2.4 (1.1, 4.6)
75%	4.6 (2.8, 12.8)	21.3 (3.5, NE)
Survival probability (95% CI) at		
Month 6	20.0% (8.8%, 34.4%)	27.8% (13.2%, 44.5%)
Month 12	14.3% (5.2%, 27.7%)	27.8% (13.2%, 44.5%)
Month 18	7.1% (1.4%, 19.6%)	27.8% (13.2%, 44.5%)
Month 24	3.6% (0.3%, 15.0%)	24.3% (10.8%, 40.8%)
Month 30	3.6% (0.3%, 15.0%)	24.3% (10.8%, 40.8%)
Month 36	NE (NE, NE)	17.4% (6.3%, 32.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.59 (0.913, 2.761)	
p-value of 2-sided stratified log-rank test	0.0924	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	33	24
0	20 (60.6%)	14 (58.3%)
1	5 (15.2%)	3 (12.5%)
2	1 (3.0%)	2 (8.3%)
3	2 (6.1%)	0
>=4	5 (15.2%)	5 (20.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	54 (80.6%)	57 (89.1%)
Censored	13 (19.4%)	7 (10.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 2.2)	1.1 (0.8, 2.1)
50%	3.5 (2.3, 5.3)	4.2 (2.2, 11.0)
75%	11.5 (5.6, 26.3)	17.5 (11.2, 27.7)
Survival probability (95% CI) at		
Month 6	33.6% (22.3%, 45.3%)	43.8% (31.4%, 55.4%)
Month 12	24.9% (14.9%, 36.3%)	35.6% (24.1%, 47.3%)
Month 18	21.0% (11.7%, 32.2%)	24.3% (14.6%, 35.4%)
Month 24	18.7% (9.8%, 29.8%)	19.1% (10.4%, 29.7%)
Month 30	9.3% (3.2%, 19.5%)	11.5% (4.9%, 21.2%)
Month 36	9.3% (3.2%, 19.5%)	5.7% (1.3%, 15.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.06 (0.723, 1.540)	
p-value of 2-sided stratified log-rank test	0.7857	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	54	57
0	34 (63.0%)	40 (70.2%)
1	5 (9.3%)	5 (8.8%)
2	5 (9.3%)	1 (1.8%)
3	3 (5.6%)	2 (3.5%)
>=4	7 (13.0%)	9 (15.8%)
p-value from Interaction Test[c]	0.1240	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	37 (41.1%)	29 (33.3%)
Censored	53 (58.9%)	58 (66.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.8, 3.7)	2.6 (1.4, 7.9)
50%	NE (6.8, NE)	NE (29.2, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	63.9% (52.8%, 73.1%)	70.0% (58.9%, 78.7%)
Month 12	55.5% (44.0%, 65.6%)	65.7% (54.2%, 75.0%)
Month 18	55.5% (44.0%, 65.6%)	65.7% (54.2%, 75.0%)
Month 24	55.5% (44.0%, 65.6%)	65.7% (54.2%, 75.0%)
Month 30	55.5% (44.0%, 65.6%)	62.2% (49.2%, 72.8%)
Month 36	55.5% (44.0%, 65.6%)	62.2% (49.2%, 72.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.78 (0.477, 1.262)	
p-value of 2-sided stratified log-rank test	0.3038	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	37	29
0	19 (51.4%)	13 (44.8%)
1	3 (8.1%)	6 (20.7%)
2	2 (5.4%)	1 (3.4%)
3	5 (13.5%)	0
>=4	8 (21.6%)	9 (31.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	11 (31.4%)	13 (39.4%)
Censored	24 (68.6%)	20 (60.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	4.1 (0.9, NE)	1.4 (0.7, 6.0)
50%	NE (23.3, NE)	NE (1.4, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	73.6% (55.3%, 85.3%)	61.8% (41.6%, 76.9%)
Month 12	73.6% (55.3%, 85.3%)	57.7% (37.4%, 73.5%)
Month 18	69.7% (50.7%, 82.5%)	52.9% (32.5%, 69.7%)
Month 24	65.3% (45.6%, 79.4%)	52.9% (32.5%, 69.7%)
Month 30	65.3% (45.6%, 79.4%)	52.9% (32.5%, 69.7%)
Month 36	65.3% (45.6%, 79.4%)	52.9% (32.5%, 69.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.80 (0.804, 4.019)	
p-value of 2-sided stratified log-rank test	0.1504	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	11	13
0	10 (90.9%)	4 (30.8%)
1	1 (9.1%)	2 (15.4%)
2	0	2 (15.4%)
3	0	0
>=4	0	5 (38.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	29 (43.3%)	29 (45.3%)
Censored	38 (56.7%)	35 (54.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.1 (0.8, 2.1)	1.4 (0.8, 2.1)
50%	NE (2.1, NE)	NE (2.2, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	53.3% (39.9%, 65.0%)	54.3% (41.1%, 65.8%)
Month 12	51.0% (37.5%, 63.0%)	54.3% (41.1%, 65.8%)
Month 18	51.0% (37.5%, 63.0%)	51.6% (38.0%, 63.6%)
Month 24	51.0% (37.5%, 63.0%)	51.6% (38.0%, 63.6%)
Month 30	51.0% (37.5%, 63.0%)	51.6% (38.0%, 63.6%)
Month 36	51.0% (37.5%, 63.0%)	51.6% (38.0%, 63.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1502 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.94 (0.561, 1.571)	
p-value of 2-sided stratified log-rank test	0.8015	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	29	29
0	6 (20.7%)	14 (48.3%)
1	3 (10.3%)	2 (6.9%)
2	5 (17.2%)	3 (10.3%)
3	0	4 (13.8%)
>=4	15 (51.7%)	6 (20.7%)
p-value from Interaction Test[c]	0.3138	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1502_c30_ttiw_dstat.sas, Output: t_2_1502_c30_ttiw_dstat.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	97 (71.9%)	96 (70.1%)
Censored	38 (28.1%)	41 (29.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (1.4, 2.2)	1.4 (0.8, 2.1)
50%	3.5 (2.8, 4.4)	3.8 (2.3, 7.4)
75%	25.3 (10.2, NE)	15.3 (10.0, 40.3)
Survival probability (95% CI) at		
Month 6	36.6% (28.3%, 44.9%)	43.2% (34.4%, 51.6%)
Month 12	30.8% (22.8%, 39.1%)	28.1% (20.0%, 36.9%)
Month 18	29.8% (21.8%, 38.1%)	21.4% (13.7%, 30.1%)
Month 24	25.7% (17.9%, 34.2%)	19.8% (12.4%, 28.6%)
Month 30	22.8% (15.2%, 31.5%)	18.0% (10.7%, 26.9%)
Month 36	16.8% (9.2%, 26.3%)	16.2% (9.1%, 25.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.91 (0.686, 1.213)	
p-value of 2-sided stratified log-rank test	0.5399	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	97	96
0	57 (58.8%)	59 (61.5%)
1	10 (10.3%)	15 (15.6%)
2	13 (13.4%)	5 (5.2%)
3	3 (3.1%)	4 (4.2%)
>=4	14 (14.4%)	13 (13.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	40 (70.2%)	33 (70.2%)
Censored	17 (29.8%)	14 (29.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.3)	0.8 (0.7, 1.4)
50%	3.0 (2.2, 3.6)	3.7 (1.2, 8.3)
75%	12.8 (3.6, NE)	27.9 (7.1, NE)
Survival probability (95% CI) at		
Month 6	36.0% (23.2%, 49.0%)	41.8% (27.3%, 55.7%)
Month 12	33.2% (20.6%, 46.5%)	34.3% (20.7%, 48.3%)
Month 18	24.2% (12.6%, 37.9%)	34.3% (20.7%, 48.3%)
Month 24	17.3% (7.2%, 31.0%)	30.0% (16.4%, 44.8%)
Month 30	13.8% (4.9%, 27.4%)	20.0% (7.7%, 36.4%)
Month 36	NE (NE, NE)	10.0% (1.0%, 31.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.02 (0.632, 1.648)	
p-value of 2-sided stratified log-rank test	0.9065	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	40	33
0	22 (55.0%)	19 (57.6%)
1	8 (20.0%)	5 (15.2%)
2	5 (12.5%)	0
3	3 (7.5%)	0
>=4	2 (5.0%)	9 (27.3%)
p-value from Interaction Test[c]	0.5097	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	110 (81.5%)	125 (91.2%)
Censored	25 (18.5%)	12 (8.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (1.4, 2.1)	1.4 (0.8, 2.1)
50%	3.5 (2.8, 4.4)	3.8 (2.3, 7.3)
75%	17.4 (9.5, 26.3)	12.6 (10.0, 15.8)
Survival probability (95% CI) at		
Month 6	36.6% (28.3%, 44.8%)	42.2% (33.8%, 50.4%)
Month 12	28.1% (20.5%, 36.1%)	26.6% (19.4%, 34.4%)
Month 18	24.5% (17.3%, 32.4%)	14.1% (8.8%, 20.7%)
Month 24	19.8% (13.2%, 27.4%)	11.7% (6.9%, 17.9%)
Month 30	16.0% (10.0%, 23.3%)	8.6% (4.6%, 14.2%)
Month 36	10.9% (5.6%, 18.1%)	6.8% (3.3%, 12.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.84 (0.645, 1.083)	
p-value of 2-sided stratified log-rank test	0.1793	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	110	125
0	70 (63.6%)	88 (70.4%)
1	10 (9.1%)	15 (12.0%)
2	13 (11.8%)	5 (4.0%)
3	3 (2.7%)	4 (3.2%)
>=4	14 (12.7%)	13 (10.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	51 (89.5%)	40 (85.1%)
Censored	6 (10.5%)	7 (14.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.2)	0.8 (0.7, 1.4)
50%	2.9 (2.2, 3.6)	3.7 (1.2, 6.1)
75%	11.1 (3.6, 20.0)	17.3 (6.0, 33.9)
Survival probability (95% CI) at		
Month 6	29.4% (18.0%, 41.6%)	40.0% (25.8%, 53.8%)
Month 12	23.9% (13.6%, 35.7%)	28.9% (16.6%, 42.4%)
Month 18	14.7% (6.9%, 25.3%)	24.1% (12.8%, 37.3%)
Month 24	11.0% (4.5%, 20.9%)	21.4% (10.7%, 34.5%)
Month 30	7.3% (2.4%, 16.2%)	12.5% (4.4%, 25.0%)
Month 36	NE (NE, NE)	8.3% (1.9%, 21.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.08 (0.698, 1.658)	
p-value of 2-sided stratified log-rank test	0.7177	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	51	40
0	33 (64.7%)	26 (65.0%)
1	8 (15.7%)	5 (12.5%)
2	5 (9.8%)	0
3	3 (5.9%)	0
>=4	2 (3.9%)	9 (22.5%)
p-value from Interaction Test[c]	0.2415	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	65 (48.1%)	66 (48.2%)
Censored	70 (51.9%)	71 (51.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (1.0, 2.6)	1.4 (0.8, 2.1)
50%	11.8 (6.0, NE)	14.9 (2.8, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	58.5% (49.4%, 66.6%)	55.6% (46.5%, 63.7%)
Month 12	49.8% (40.5%, 58.4%)	52.6% (43.4%, 61.0%)
Month 18	47.5% (38.2%, 56.3%)	49.0% (39.6%, 57.7%)
Month 24	46.1% (36.7%, 55.1%)	47.5% (38.0%, 56.4%)
Month 30	46.1% (36.7%, 55.1%)	47.5% (38.0%, 56.4%)
Month 36	46.1% (36.7%, 55.1%)	42.6% (31.9%, 52.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.02 (0.725, 1.445)	
p-value of 2-sided stratified log-rank test	0.8987	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	65	66
0	37 (56.9%)	33 (50.0%)
1	8 (12.3%)	7 (10.6%)
2	2 (3.1%)	7 (10.6%)
3	3 (4.6%)	5 (7.6%)
>=4	15 (23.1%)	14 (21.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	24 (42.1%)	25 (53.2%)
Censored	33 (57.9%)	22 (46.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 3.3)	1.4 (0.8, 1.7)
50%	NE (3.0, NE)	3.5 (1.6, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	57.4% (42.8%, 69.6%)	48.8% (33.6%, 62.3%)
Month 12	51.5% (36.4%, 64.7%)	46.1% (31.0%, 59.9%)
Month 18	51.5% (36.4%, 64.7%)	46.1% (31.0%, 59.9%)
Month 24	51.5% (36.4%, 64.7%)	46.1% (31.0%, 59.9%)
Month 30	51.5% (36.4%, 64.7%)	41.9% (26.4%, 56.6%)
Month 36	51.5% (36.4%, 64.7%)	41.9% (26.4%, 56.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Global QOL Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.09 (0.613, 1.941)	
p-value of 2-sided stratified log-rank test	0.7357	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	24	25
0	14 (58.3%)	11 (44.0%)
1	1 (4.2%)	3 (12.0%)
2	3 (12.5%)	4 (16.0%)
3	1 (4.2%)	4 (16.0%)
>=4	5 (20.8%)	3 (12.0%)
p-value from Interaction Test[c]	0.7454	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	96 (71.1%)	89 (65.0%)
Censored	39 (28.9%)	48 (35.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (1.2, 1.6)	1.6 (1.4, 2.1)
50%	3.0 (2.2, 3.7)	4.6 (2.8, 9.6)
75%	24.0 (6.0, NE)	24.3 (15.9, NE)
Survival probability (95% CI) at		
Month 6	33.9% (25.8%, 42.1%)	48.8% (39.8%, 57.2%)
Month 12	32.2% (24.2%, 40.4%)	40.0% (31.1%, 48.7%)
Month 18	28.3% (20.4%, 36.8%)	30.9% (22.2%, 40.1%)
Month 24	24.1% (16.3%, 32.7%)	25.0% (16.6%, 34.4%)
Month 30	22.5% (14.8%, 31.2%)	18.3% (10.5%, 27.7%)
Month 36	18.4% (10.8%, 27.6%)	18.3% (10.5%, 27.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.16 (0.869, 1.558)	
p-value of 2-sided stratified log-rank test	0.3095	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	96	89
0	42 (43.8%)	40 (44.9%)
1	24 (25.0%)	15 (16.9%)
2	4 (4.2%)	7 (7.9%)
3	9 (9.4%)	5 (5.6%)
>=4	17 (17.7%)	22 (24.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	37 (64.9%)	34 (72.3%)
Censored	20 (35.1%)	13 (27.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.5)	2.1 (0.9, 2.8)
50%	2.2 (1.3, 6.1)	3.5 (2.8, 6.9)
75%	15.4 (6.1, NE)	27.9 (5.6, NE)
Survival probability (95% CI) at		
Month 6	38.2% (25.0%, 51.2%)	38.9% (24.7%, 53.0%)
Month 12	35.5% (22.4%, 48.7%)	29.0% (16.3%, 43.0%)
Month 18	22.2% (10.5%, 36.5%)	26.1% (13.9%, 40.1%)
Month 24	22.2% (10.5%, 36.5%)	26.1% (13.9%, 40.1%)
Month 30	22.2% (10.5%, 36.5%)	21.8% (10.0%, 36.4%)
Month 36	22.2% (10.5%, 36.5%)	10.9% (1.2%, 32.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.22 (0.750, 1.972)	
p-value of 2-sided stratified log-rank test	0.4243	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	37	34
0	17 (45.9%)	17 (50.0%)
1	6 (16.2%)	5 (14.7%)
2	3 (8.1%)	1 (2.9%)
3	2 (5.4%)	1 (2.9%)
>=4	9 (24.3%)	10 (29.4%)
p-value from Interaction Test[c]	0.9268	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	110 (81.5%)	121 (88.3%)
Censored	25 (18.5%)	16 (11.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (1.1, 1.6)	1.6 (1.4, 2.1)
50%	3.0 (2.2, 3.7)	4.6 (2.8, 8.2)
75%	19.5 (6.5, 26.3)	16.1 (13.3, 21.9)
Survival probability (95% CI) at		
Month 6	34.0% (26.0%, 42.1%)	47.0% (38.4%, 55.2%)
Month 12	30.7% (23.0%, 38.8%)	35.3% (27.3%, 43.5%)
Month 18	26.1% (18.7%, 34.0%)	21.7% (15.0%, 29.2%)
Month 24	19.1% (12.5%, 26.7%)	15.3% (9.6%, 22.1%)
Month 30	15.1% (9.1%, 22.3%)	9.6% (5.3%, 15.5%)
Month 36	11.3% (6.0%, 18.4%)	8.6% (4.4%, 14.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.02 (0.786, 1.327)	
p-value of 2-sided stratified log-rank test	0.8812	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	110	121
0	56 (50.9%)	72 (59.5%)
1	24 (21.8%)	15 (12.4%)
2	4 (3.6%)	7 (5.8%)
3	9 (8.2%)	5 (4.1%)
>=4	17 (15.5%)	22 (18.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	50 (87.7%)	39 (83.0%)
Censored	7 (12.3%)	8 (17.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.5)	2.1 (0.9, 2.8)
50%	2.2 (1.5, 4.9)	3.5 (2.8, 6.7)
75%	9.6 (4.9, 18.7)	16.7 (5.6, 33.9)
Survival probability (95% CI) at		
Month 6	32.4% (20.4%, 44.9%)	37.8% (23.9%, 51.6%)
Month 12	24.3% (13.7%, 36.5%)	28.9% (16.6%, 42.4%)
Month 18	14.2% (6.3%, 25.1%)	24.1% (12.8%, 37.3%)
Month 24	10.1% (3.8%, 20.2%)	19.3% (9.2%, 32.0%)
Month 30	8.1% (2.6%, 17.6%)	14.0% (5.6%, 26.2%)
Month 36	6.1% (1.6%, 15.0%)	7.0% (0.8%, 23.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.35 (0.872, 2.089)	
p-value of 2-sided stratified log-rank test	0.1766	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	50	39
0	30 (60.0%)	22 (56.4%)
1	6 (12.0%)	5 (12.8%)
2	3 (6.0%)	1 (2.6%)
3	2 (4.0%)	1 (2.6%)
>=4	9 (18.0%)	10 (25.6%)
p-value from Interaction Test[c]	0.3060	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	50 (37.0%)	49 (35.8%)
Censored	85 (63.0%)	88 (64.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	4.1 (1.5, 8.7)	4.2 (1.4, 6.9)
50%	NE (22.5, NE)	NE (15.3, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	72.2% (63.6%, 79.1%)	69.3% (60.4%, 76.5%)
Month 12	64.8% (55.6%, 72.5%)	62.4% (53.0%, 70.4%)
Month 18	63.6% (54.4%, 71.5%)	58.7% (48.9%, 67.2%)
Month 24	59.6% (49.7%, 68.1%)	58.7% (48.9%, 67.2%)
Month 30	56.6% (46.3%, 65.5%)	58.7% (48.9%, 67.2%)
Month 36	56.6% (46.3%, 65.5%)	58.7% (48.9%, 67.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.94 (0.631, 1.401)	
p-value of 2-sided stratified log-rank test	0.7717	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	50	49
0	24 (48.0%)	19 (38.8%)
1	4 (8.0%)	9 (18.4%)
2	6 (12.0%)	4 (8.2%)
3	2 (4.0%)	6 (12.2%)
>=4	14 (28.0%)	11 (22.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	20 (35.1%)	13 (27.7%)
Censored	37 (64.9%)	34 (72.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	4.6 (0.9, 16.8)	5.6 (0.8, NE)
50%	31.4 (9.9, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	69.5% (54.3%, 80.5%)	72.8% (57.0%, 83.6%)
Month 12	63.4% (47.3%, 75.8%)	69.8% (53.4%, 81.3%)
Month 18	59.9% (43.2%, 73.1%)	69.8% (53.4%, 81.3%)
Month 24	59.9% (43.2%, 73.1%)	69.8% (53.4%, 81.3%)
Month 30	59.9% (43.2%, 73.1%)	69.8% (53.4%, 81.3%)
Month 36	47.9% (28.2%, 65.2%)	69.8% (53.4%, 81.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Physical Functioning Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.66 (0.322, 1.334)	
p-value of 2-sided stratified log-rank test	0.2404	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	20	13
0	11 (55.0%)	5 (38.5%)
1	5 (25.0%)	3 (23.1%)
2	0	3 (23.1%)
3	4 (20.0%)	0
>=4	0	2 (15.4%)
p-value from Interaction Test[c]	0.3628	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	104 (77.0%)	96 (70.1%)
Censored	31 (23.0%)	41 (29.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.5)	1.4 (0.9, 1.7)
50%	2.8 (2.1, 3.0)	3.5 (2.1, 4.6)
75%	11.3 (4.2, 30.9)	17.7 (10.0, 31.9)
Survival probability (95% CI) at		
Month 6	27.7% (20.3%, 35.6%)	40.4% (31.7%, 48.8%)
Month 12	24.0% (16.9%, 31.8%)	30.0% (21.8%, 38.5%)
Month 18	21.9% (15.0%, 29.6%)	24.8% (16.9%, 33.5%)
Month 24	18.6% (11.8%, 26.7%)	19.6% (12.3%, 28.1%)
Month 30	16.9% (10.2%, 25.1%)	19.6% (12.3%, 28.1%)
Month 36	15.0% (8.5%, 23.4%)	16.0% (9.1%, 24.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.16 (0.874, 1.537)	
p-value of 2-sided stratified log-rank test	0.3001	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	104	96
0	43 (41.3%)	53 (55.2%)
1	19 (18.3%)	16 (16.7%)
2	5 (4.8%)	10 (10.4%)
3	10 (9.6%)	4 (4.2%)
>=4	27 (26.0%)	13 (13.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	41 (71.9%)	36 (76.6%)
Censored	16 (28.1%)	11 (23.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.5)	1.4 (0.8, 1.5)
50%	2.4 (1.5, 3.7)	2.8 (1.4, 4.2)
75%	12.8 (3.7, NE)	12.9 (3.5, NE)
Survival probability (95% CI) at		
Month 6	32.3% (19.9%, 45.2%)	33.3% (20.2%, 47.0%)
Month 12	26.3% (14.5%, 39.7%)	30.8% (18.0%, 44.5%)
Month 18	19.7% (9.1%, 33.4%)	20.5% (9.3%, 34.7%)
Month 24	13.1% (4.6%, 26.3%)	16.4% (6.2%, 30.8%)
Month 30	13.1% (4.6%, 26.3%)	12.3% (3.6%, 26.6%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.01 (0.629, 1.612)	
p-value of 2-sided stratified log-rank test	0.9795	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	41	36
0	16 (39.0%)	11 (30.6%)
1	13 (31.7%)	7 (19.4%)
2	2 (4.9%)	4 (11.1%)
3	2 (4.9%)	1 (2.8%)
>=4	8 (19.5%)	13 (36.1%)
p-value from Interaction Test[c]	0.5124	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	116 (85.9%)	121 (88.3%)
Censored	19 (14.1%)	16 (11.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.4)	1.4 (0.9, 1.7)
50%	2.7 (2.1, 3.0)	3.5 (2.1, 4.6)
75%	9.5 (4.2, 20.1)	13.2 (10.0, 17.5)
Survival probability (95% CI) at		
Month 6	28.0% (20.6%, 35.8%)	38.8% (30.6%, 47.0%)
Month 12	22.4% (15.7%, 29.9%)	27.5% (20.2%, 35.4%)
Month 18	19.9% (13.5%, 27.2%)	17.0% (11.1%, 24.0%)
Month 24	13.0% (7.6%, 19.8%)	12.1% (7.2%, 18.5%)
Month 30	11.0% (6.1%, 17.5%)	10.5% (5.9%, 16.6%)
Month 36	8.6% (4.3%, 15.0%)	8.8% (4.6%, 14.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.09 (0.843, 1.414)	
p-value of 2-sided stratified log-rank test	0.5066	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	116	121
0	55 (47.4%)	78 (64.5%)
1	19 (16.4%)	16 (13.2%)
2	5 (4.3%)	10 (8.3%)
3	10 (8.6%)	4 (3.3%)
>=4	27 (23.3%)	13 (10.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	51 (89.5%)	41 (87.2%)
Censored	6 (10.5%)	6 (12.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.5)	1.4 (0.8, 1.5)
50%	2.3 (1.5, 3.7)	2.8 (1.4, 4.2)
75%	6.1 (3.7, 13.2)	12.6 (3.5, 21.7)
Survival probability (95% CI) at		
Month 6	27.5% (16.5%, 39.7%)	33.3% (20.2%, 47.0%)
Month 12	17.7% (8.9%, 29.0%)	26.5% (14.7%, 39.9%)
Month 18	11.8% (4.9%, 22.1%)	16.9% (7.6%, 29.3%)
Month 24	7.9% (2.5%, 17.2%)	12.0% (4.5%, 23.6%)
Month 30	5.9% (1.6%, 14.6%)	7.2% (1.9%, 17.5%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.12 (0.726, 1.718)	
p-value of 2-sided stratified log-rank test	0.6117	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	51	41
0	26 (51.0%)	16 (39.0%)
1	13 (25.5%)	7 (17.1%)
2	2 (3.9%)	4 (9.8%)
3	2 (3.9%)	1 (2.4%)
>=4	8 (15.7%)	13 (31.7%)
p-value from Interaction Test[c]	0.9746	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	54 (40.0%)	55 (40.1%)
Censored	81 (60.0%)	82 (59.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.1 (0.8, 2.1)	1.4 (0.9, 2.1)
50%	NE (10.8, NE)	NE (12.7, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	60.7% (51.7%, 68.5%)	62.0% (53.0%, 69.8%)
Month 12	58.6% (49.5%, 66.7%)	59.9% (50.7%, 67.9%)
Month 18	57.5% (48.2%, 65.6%)	56.2% (46.6%, 64.7%)
Month 24	57.5% (48.2%, 65.6%)	54.5% (44.7%, 63.3%)
Month 30	57.5% (48.2%, 65.6%)	54.5% (44.7%, 63.3%)
Month 36	57.5% (48.2%, 65.6%)	54.5% (44.7%, 63.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.95 (0.647, 1.384)	
p-value of 2-sided stratified log-rank test	0.7727	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	54	55
0	22 (40.7%)	24 (43.6%)
1	9 (16.7%)	4 (7.3%)
2	5 (9.3%)	3 (5.5%)
3	1 (1.9%)	5 (9.1%)
>=4	17 (31.5%)	19 (34.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	25 (43.9%)	16 (34.0%)
Censored	32 (56.1%)	31 (66.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.8)	1.4 (0.8, NE)
50%	23.6 (2.8, NE)	NE (10.5, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	56.3% (41.4%, 68.8%)	71.1% (55.5%, 82.1%)
Month 12	50.7% (35.4%, 64.0%)	62.9% (46.5%, 75.6%)
Month 18	50.7% (35.4%, 64.0%)	62.9% (46.5%, 75.6%)
Month 24	46.1% (29.9%, 60.7%)	62.9% (46.5%, 75.6%)
Month 30	46.1% (29.9%, 60.7%)	62.9% (46.5%, 75.6%)
Month 36	46.1% (29.9%, 60.7%)	62.9% (46.5%, 75.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Role Functioning Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.69 (0.364, 1.314)	
p-value of 2-sided stratified log-rank test	0.2565	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	25	16
0	12 (48.0%)	5 (31.3%)
1	6 (24.0%)	5 (31.3%)
2	2 (8.0%)	1 (6.3%)
3	1 (4.0%)	0
>=4	4 (16.0%)	5 (31.3%)
p-value from Interaction Test[c]	0.3951	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	70 (51.9%)	70 (51.1%)
Censored	65 (48.1%)	67 (48.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.1 (2.2, 4.0)	2.1 (1.4, 3.5)
50%	14.3 (7.1, 37.5)	13.0 (6.6, 31.1)
75%	NE (NE, NE)	NE (38.9, NE)
Survival probability (95% CI) at		
Month 6	60.2% (51.2%, 68.1%)	61.5% (52.4%, 69.4%)
Month 12	50.2% (41.0%, 58.7%)	50.7% (41.3%, 59.4%)
Month 18	45.4% (36.0%, 54.3%)	45.9% (36.3%, 54.9%)
Month 24	45.4% (36.0%, 54.3%)	42.7% (32.9%, 52.2%)
Month 30	42.2% (32.6%, 51.6%)	42.7% (32.9%, 52.2%)
Month 36	40.6% (30.9%, 50.1%)	36.6% (26.2%, 47.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.91 (0.651, 1.269)	
p-value of 2-sided stratified log-rank test	0.5819	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	70	70
0	44 (62.9%)	39 (55.7%)
1	16 (22.9%)	15 (21.4%)
2	6 (8.6%)	4 (5.7%)
3	2 (2.9%)	4 (5.7%)
>=4	2 (2.9%)	8 (11.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	28 (49.1%)	30 (63.8%)
Censored	29 (50.9%)	17 (36.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.4 (1.7, 4.7)	2.2 (1.0, 2.8)
50%	13.9 (4.3, NE)	6.1 (2.8, 11.4)
75%	NE (21.7, NE)	NE (8.1, NE)
Survival probability (95% CI) at		
Month 6	62.0% (47.0%, 73.9%)	50.2% (34.7%, 63.9%)
Month 12	53.8% (38.2%, 67.0%)	34.7% (20.8%, 49.1%)
Month 18	44.9% (29.4%, 59.3%)	31.9% (18.3%, 46.3%)
Month 24	35.3% (20.5%, 50.4%)	28.3% (15.1%, 43.0%)
Month 30	35.3% (20.5%, 50.4%)	28.3% (15.1%, 43.0%)
Month 36	35.3% (20.5%, 50.4%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.67 (0.391, 1.148)	
p-value of 2-sided stratified log-rank test	0.1361	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	28	30
0	15 (53.6%)	18 (60.0%)
1	7 (25.0%)	5 (16.7%)
2	2 (7.1%)	2 (6.7%)
3	2 (7.1%)	2 (6.7%)
>=4	2 (7.1%)	3 (10.0%)
p-value from Interaction Test[c]	0.5631	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	95 (70.4%)	112 (81.8%)
Censored	40 (29.6%)	25 (18.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.9 (2.1, 4.0)	2.1 (1.4, 3.5)
50%	9.6 (6.1, 15.8)	9.4 (6.1, 12.6)
75%	32.1 (20.3, NE)	22.6 (17.3, 31.3)
Survival probability (95% CI) at		
Month 6	59.6% (50.6%, 67.4%)	59.0% (50.2%, 66.8%)
Month 12	45.8% (36.9%, 54.1%)	43.7% (35.2%, 51.9%)
Month 18	38.8% (30.2%, 47.3%)	30.7% (23.0%, 38.6%)
Month 24	32.2% (24.0%, 40.6%)	24.2% (17.2%, 31.8%)
Month 30	27.4% (19.7%, 35.8%)	20.0% (13.5%, 27.3%)
Month 36	23.4% (16.0%, 31.6%)	17.2% (11.2%, 24.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.81 (0.614, 1.065)	
p-value of 2-sided stratified log-rank test	0.1332	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	95	112
0	69 (72.6%)	81 (72.3%)
1	16 (16.8%)	15 (13.4%)
2	6 (6.3%)	4 (3.6%)
3	2 (2.1%)	4 (3.6%)
>=4	2 (2.1%)	8 (7.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	44 (77.2%)	39 (83.0%)
Censored	13 (22.8%)	8 (17.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.4 (1.7, 3.6)	2.2 (1.0, 2.8)
50%	6.1 (3.6, 13.2)	5.6 (2.8, 8.1)
75%	21.1 (13.2, NE)	19.0 (7.0, 32.9)
Survival probability (95% CI) at		
Month 6	51.7% (37.6%, 64.1%)	48.9% (33.7%, 62.4%)
Month 12	42.1% (28.8%, 54.9%)	31.1% (18.4%, 44.7%)
Month 18	28.7% (17.3%, 41.2%)	26.7% (14.9%, 40.0%)
Month 24	21.1% (11.3%, 32.9%)	20.0% (9.9%, 32.6%)
Month 30	19.0% (9.7%, 30.6%)	20.0% (9.9%, 32.6%)
Month 36	15.2% (6.4%, 27.5%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.85 (0.539, 1.353)	
p-value of 2-sided stratified log-rank test	0.4917	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	44	39
0	31 (70.5%)	27 (69.2%)
1	7 (15.9%)	5 (12.8%)
2	2 (4.5%)	2 (5.1%)
3	2 (4.5%)	2 (5.1%)
>=4	2 (4.5%)	3 (7.7%)
p-value from Interaction Test[c]	0.7292	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	71 (52.6%)	59 (43.1%)
Censored	64 (47.4%)	78 (56.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.3 (0.8, 2.1)	1.4 (0.8, 2.1)
50%	8.7 (3.7, 31.9)	NE (4.4, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	55.0% (45.9%, 63.1%)	58.8% (49.7%, 66.7%)
Month 12	47.0% (37.8%, 55.7%)	54.8% (45.6%, 63.1%)
Month 18	44.3% (34.9%, 53.2%)	54.8% (45.6%, 63.1%)
Month 24	41.4% (31.9%, 50.6%)	53.2% (43.7%, 61.8%)
Month 30	41.4% (31.9%, 50.6%)	53.2% (43.7%, 61.8%)
Month 36	39.3% (29.4%, 48.9%)	50.2% (39.6%, 60.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.80 (0.567, 1.141)	
p-value of 2-sided stratified log-rank test	0.2088	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	71	59
0	35 (49.3%)	31 (52.5%)
1	9 (12.7%)	12 (20.3%)
2	11 (15.5%)	3 (5.1%)
3	4 (5.6%)	3 (5.1%)
>=4	12 (16.9%)	10 (16.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	27 (47.4%)	23 (48.9%)
Censored	30 (52.6%)	24 (51.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.9)	1.2 (0.8, 1.7)
50%	11.0 (2.8, NE)	12.5 (1.5, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	59.6% (44.9%, 71.5%)	51.1% (35.8%, 64.5%)
Month 12	48.4% (33.2%, 62.1%)	51.1% (35.8%, 64.5%)
Month 18	45.2% (29.9%, 59.3%)	47.5% (31.8%, 61.6%)
Month 24	41.1% (25.5%, 56.0%)	47.5% (31.8%, 61.6%)
Month 30	41.1% (25.5%, 56.0%)	47.5% (31.8%, 61.6%)
Month 36	NE (NE, NE)	47.5% (31.8%, 61.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Emotional Functioning Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.19 (0.666, 2.113)	
p-value of 2-sided stratified log-rank test	0.5668	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	27	23
0	15 (55.6%)	10 (43.5%)
1	7 (25.9%)	5 (21.7%)
2	0	1 (4.3%)
3	1 (3.7%)	1 (4.3%)
>=4	4 (14.8%)	6 (26.1%)
p-value from Interaction Test[c]	0.2942	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	105 (77.8%)	108 (78.8%)
Censored	30 (22.2%)	29 (21.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.1 (0.8, 1.4)	1.3 (0.8, 1.4)
50%	3.1 (2.1, 4.1)	2.2 (2.1, 3.6)
75%	13.9 (5.8, 29.3)	12.2 (5.8, 17.7)
Survival probability (95% CI) at		
Month 6	32.3% (24.5%, 40.4%)	30.4% (22.6%, 38.6%)
Month 12	26.5% (19.0%, 34.5%)	25.7% (18.3%, 33.7%)
Month 18	21.6% (14.4%, 29.7%)	16.6% (10.2%, 24.3%)
Month 24	20.1% (12.9%, 28.3%)	16.6% (10.2%, 24.3%)
Month 30	15.0% (8.4%, 23.5%)	10.2% (4.8%, 17.9%)
Month 36	10.7% (4.8%, 19.4%)	8.5% (3.6%, 16.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.93 (0.705, 1.223)	
p-value of 2-sided stratified log-rank test	0.6160	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	105	108
0	52 (49.5%)	64 (59.3%)
1	22 (21.0%)	16 (14.8%)
2	7 (6.7%)	3 (2.8%)
3	8 (7.6%)	7 (6.5%)
>=4	16 (15.2%)	18 (16.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	35 (61.4%)	34 (72.3%)
Censored	22 (38.6%)	13 (27.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 2.0)	1.3 (0.8, 2.1)
50%	4.4 (2.0, 17.6)	3.0 (2.1, 5.8)
75%	28.4 (15.4, NE)	27.9 (5.6, NE)
Survival probability (95% CI) at		
Month 6	46.3% (31.9%, 59.5%)	35.6% (22.0%, 49.3%)
Month 12	41.0% (26.8%, 54.6%)	28.0% (15.7%, 41.7%)
Month 18	34.7% (20.8%, 49.0%)	28.0% (15.7%, 41.7%)
Month 24	31.2% (17.6%, 45.8%)	28.0% (15.7%, 41.7%)
Month 30	23.4% (10.9%, 38.6%)	19.2% (7.8%, 34.3%)
Month 36	0 (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.77 (0.469, 1.254)	
p-value of 2-sided stratified log-rank test	0.2911	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	35	34
0	19 (54.3%)	19 (55.9%)
1	7 (20.0%)	7 (20.6%)
2	3 (8.6%)	1 (2.9%)
3	1 (2.9%)	2 (5.9%)
>=4	5 (14.3%)	5 (14.7%)
p-value from Interaction Test[c]	0.5647	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	120 (88.9%)	127 (92.7%)
Censored	15 (11.1%)	10 (7.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.1 (0.8, 1.4)	1.2 (0.8, 1.4)
50%	3.0 (2.1, 4.1)	2.3 (2.1, 3.7)
75%	11.5 (5.8, 18.2)	10.0 (5.8, 15.5)
Survival probability (95% CI) at		
Month 6	32.5% (24.7%, 40.5%)	30.3% (22.7%, 38.1%)
Month 12	24.3% (17.2%, 32.0%)	23.3% (16.6%, 30.8%)
Month 18	18.1% (11.9%, 25.4%)	13.2% (8.1%, 19.6%)
Month 24	12.7% (7.4%, 19.3%)	10.0% (5.6%, 15.9%)
Month 30	8.1% (4.1%, 14.0%)	5.0% (2.1%, 9.8%)
Month 36	5.8% (2.4%, 11.4%)	4.1% (1.6%, 8.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.95 (0.737, 1.229)	
p-value of 2-sided stratified log-rank test	0.7267	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	120	127
0	67 (55.8%)	83 (65.4%)
1	22 (18.3%)	16 (12.6%)
2	7 (5.8%)	3 (2.4%)
3	8 (6.7%)	7 (5.5%)
>=4	16 (13.3%)	18 (14.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	49 (86.0%)	40 (85.1%)
Censored	8 (14.0%)	7 (14.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 2.0)	1.3 (0.8, 2.1)
50%	3.6 (2.0, 6.1)	3.0 (2.1, 5.8)
75%	17.6 (6.0, 26.5)	12.9 (5.6, 28.4)
Survival probability (95% CI) at		
Month 6	37.4% (24.8%, 50.1%)	35.6% (22.0%, 49.3%)
Month 12	30.0% (18.4%, 42.4%)	26.7% (14.9%, 40.0%)
Month 18	24.3% (13.9%, 36.3%)	22.2% (11.5%, 35.1%)
Month 24	20.6% (11.0%, 32.2%)	17.3% (7.9%, 29.7%)
Month 30	11.2% (4.6%, 21.2%)	12.3% (4.7%, 24.0%)
Month 36	0 (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.85 (0.551, 1.313)	
p-value of 2-sided stratified log-rank test	0.4697	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	49	40
0	33 (67.3%)	25 (62.5%)
1	7 (14.3%)	7 (17.5%)
2	3 (6.1%)	1 (2.5%)
3	1 (2.0%)	2 (5.0%)
>=4	5 (10.2%)	5 (12.5%)
p-value from Interaction Test[c]	0.7363	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	46 (34.1%)	45 (32.8%)
Censored	89 (65.9%)	92 (67.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.8 (1.5, 8.3)	2.8 (1.6, 8.8)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	69.7% (61.0%, 76.9%)	70.1% (61.3%, 77.3%)
Month 12	65.8% (56.7%, 73.5%)	66.2% (57.0%, 73.9%)
Month 18	64.7% (55.5%, 72.5%)	65.0% (55.6%, 72.8%)
Month 24	64.7% (55.5%, 72.5%)	65.0% (55.6%, 72.8%)
Month 30	61.1% (50.9%, 69.7%)	63.3% (53.6%, 71.5%)
Month 36	61.1% (50.9%, 69.7%)	61.3% (51.1%, 70.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.97 (0.641, 1.479)	
p-value of 2-sided stratified log-rank test	0.8984	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	46	45
0	21 (45.7%)	28 (62.2%)
1	15 (32.6%)	10 (22.2%)
2	4 (8.7%)	2 (4.4%)
3	3 (6.5%)	1 (2.2%)
>=4	3 (6.5%)	4 (8.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	21 (36.8%)	17 (36.2%)
Censored	36 (63.2%)	30 (63.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.5 (0.8, 3.5)	0.9 (0.8, 22.1)
50%	NE (3.5, NE)	NE (9.6, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	63.1% (48.3%, 74.7%)	66.6% (50.8%, 78.3%)
Month 12	56.9% (41.3%, 69.8%)	63.3% (46.9%, 75.8%)
Month 18	56.9% (41.3%, 69.8%)	63.3% (46.9%, 75.8%)
Month 24	56.9% (41.3%, 69.8%)	59.0% (41.7%, 72.8%)
Month 30	56.9% (41.3%, 69.8%)	59.0% (41.7%, 72.8%)
Month 36	NE (NE, NE)	59.0% (41.7%, 72.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Cognitive Functioning Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.88 (0.453, 1.712)	
p-value of 2-sided stratified log-rank test	0.7183	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	21	17
0	9 (42.9%)	5 (29.4%)
1	6 (28.6%)	5 (29.4%)
2	2 (9.5%)	1 (5.9%)
3	2 (9.5%)	3 (17.6%)
>=4	2 (9.5%)	3 (17.6%)
p-value from Interaction Test[c]	0.8851	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	100 (74.1%)	95 (69.3%)
Censored	35 (25.9%)	42 (30.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.4)	1.0 (0.8, 1.4)
50%	2.8 (2.1, 3.5)	3.0 (2.1, 4.6)
75%	13.9 (4.4, NE)	21.3 (13.0, NE)
Survival probability (95% CI) at		
Month 6	27.9% (20.4%, 35.9%)	39.7% (31.1%, 48.2%)
Month 12	25.1% (17.9%, 33.0%)	33.4% (25.0%, 42.0%)
Month 18	24.0% (16.8%, 31.9%)	25.2% (17.3%, 33.9%)
Month 24	22.3% (15.0%, 30.4%)	22.2% (14.5%, 31.0%)
Month 30	20.3% (12.9%, 28.8%)	19.1% (11.7%, 27.9%)
Month 36	18.0% (10.6%, 26.9%)	17.4% (10.2%, 26.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.08 (0.810, 1.436)	
p-value of 2-sided stratified log-rank test	0.6127	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	100	95
0	54 (54.0%)	54 (56.8%)
1	14 (14.0%)	15 (15.8%)
2	7 (7.0%)	4 (4.2%)
3	9 (9.0%)	5 (5.3%)
>=4	16 (16.0%)	17 (17.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	39 (68.4%)	30 (63.8%)
Censored	18 (31.6%)	17 (36.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.7, 1.4)	1.4 (0.8, 2.2)
50%	2.4 (1.4, 5.6)	5.5 (2.1, 12.9)
75%	15.4 (5.6, NE)	30.9 (12.6, NE)
Survival probability (95% CI) at		
Month 6	35.8% (22.7%, 49.1%)	46.0% (30.9%, 59.8%)
Month 12	29.3% (16.5%, 43.2%)	39.9% (25.0%, 54.3%)
Month 18	22.8% (11.1%, 36.9%)	33.2% (18.9%, 48.2%)
Month 24	19.5% (8.7%, 33.5%)	29.1% (15.1%, 44.6%)
Month 30	14.6% (4.9%, 29.4%)	29.1% (15.1%, 44.6%)
Month 36	NE (NE, NE)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.23 (0.757, 2.011)	
p-value of 2-sided stratified log-rank test	0.4064	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	39	30
0	23 (59.0%)	13 (43.3%)
1	3 (7.7%)	1 (3.3%)
2	5 (12.8%)	4 (13.3%)
3	1 (2.6%)	2 (6.7%)
>=4	7 (17.9%)	10 (33.3%)
p-value from Interaction Test[c]	0.5832	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	114 (84.4%)	123 (89.8%)
Censored	21 (15.6%)	14 (10.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.0 (0.8, 1.4)	1.0 (0.8, 1.4)
50%	2.8 (2.1, 3.5)	3.3 (2.1, 4.6)
75%	9.5 (4.6, 20.1)	13.0 (9.9, 17.3)
Survival probability (95% CI) at		
Month 6	28.2% (20.8%, 36.1%)	37.4% (29.2%, 45.5%)
Month 12	23.2% (16.3%, 30.8%)	28.0% (20.7%, 35.8%)
Month 18	21.4% (14.7%, 29.0%)	17.1% (11.2%, 24.1%)
Month 24	15.0% (9.1%, 22.2%)	13.2% (8.1%, 19.7%)
Month 30	11.8% (6.5%, 18.7%)	9.3% (5.1%, 15.1%)
Month 36	9.3% (4.6%, 16.0%)	6.7% (3.1%, 12.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.02 (0.784, 1.324)	
p-value of 2-sided stratified log-rank test	0.8983	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	114	123
0	68 (59.6%)	82 (66.7%)
1	14 (12.3%)	15 (12.2%)
2	7 (6.1%)	4 (3.3%)
3	9 (7.9%)	5 (4.1%)
>=4	16 (14.0%)	17 (13.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	53 (93.0%)	39 (83.0%)
Censored	4 (7.0%)	8 (17.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	0.9 (0.8, 1.4)	1.4 (0.8, 2.2)
50%	2.3 (1.4, 4.6)	3.8 (2.1, 10.3)
75%	6.5 (4.9, 13.2)	18.2 (9.4, 31.7)
Survival probability (95% CI) at		
Month 6	28.6% (17.5%, 40.7%)	44.4% (29.7%, 58.2%)
Month 12	17.9% (9.2%, 28.8%)	35.1% (21.5%, 49.0%)
Month 18	12.5% (5.5%, 22.5%)	25.7% (14.0%, 39.2%)
Month 24	10.7% (4.4%, 20.3%)	18.2% (8.4%, 31.0%)
Month 30	5.4% (1.4%, 13.4%)	18.2% (8.4%, 31.0%)
Month 36	NE (NE, NE)	12.1% (4.2%, 24.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.32 (0.856, 2.035)	
p-value of 2-sided stratified log-rank test	0.2043	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	53	39
0	37 (69.8%)	22 (56.4%)
1	3 (5.7%)	1 (2.6%)
2	5 (9.4%)	4 (10.3%)
3	1 (1.9%)	2 (5.1%)
>=4	7 (13.2%)	10 (25.6%)
p-value from Interaction Test[c]	0.3215	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	55 (40.7%)	60 (43.8%)
Censored	80 (59.3%)	77 (56.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.8 (0.9, 3.0)	1.4 (0.9, 2.1)
50%	NE (10.4, NE)	NE (5.2, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	62.8% (53.9%, 70.5%)	58.2% (49.1%, 66.2%)
Month 12	58.2% (49.0%, 66.3%)	55.4% (46.2%, 63.6%)
Month 18	57.0% (47.8%, 65.3%)	52.9% (43.5%, 61.4%)
Month 24	55.7% (46.3%, 64.2%)	52.9% (43.5%, 61.4%)
Month 30	55.7% (46.3%, 64.2%)	50.9% (41.1%, 59.9%)
Month 36	55.7% (46.3%, 64.2%)	50.9% (41.1%, 59.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.15 (0.798, 1.667)	
p-value of 2-sided stratified log-rank test	0.4591	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	55	60
0	26 (47.3%)	25 (41.7%)
1	6 (10.9%)	10 (16.7%)
2	4 (7.3%)	6 (10.0%)
3	3 (5.5%)	3 (5.0%)
>=4	16 (29.1%)	16 (26.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	22 (38.6%)	11 (23.4%)
Censored	35 (61.4%)	36 (76.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (0.8, 3.0)	6.3 (1.4, NE)
50%	NE (3.0, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	60.7% (45.8%, 72.6%)	77.4% (62.0%, 87.2%)
Month 12	55.2% (39.9%, 68.1%)	74.8% (59.1%, 85.2%)
Month 18	55.2% (39.9%, 68.1%)	74.8% (59.1%, 85.2%)
Month 24	55.2% (39.9%, 68.1%)	74.8% (59.1%, 85.2%)
Month 30	55.2% (39.9%, 68.1%)	74.8% (59.1%, 85.2%)
Month 36	55.2% (39.9%, 68.1%)	74.8% (59.1%, 85.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.1402 Kaplan Meier Analysis of EORTC-QLQ-C30 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EORTC Social Functioning Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.45 (0.211, 0.947)	
p-value of 2-sided stratified log-rank test	0.0325	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	22	11
0	9 (40.9%)	6 (54.5%)
1	1 (4.5%)	0
2	3 (13.6%)	0
3	2 (9.1%)	1 (9.1%)
>=4	7 (31.8%)	4 (36.4%)
p-value from Interaction Test[c]	0.0349	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-C30 Global health status/QoL and Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-C30 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_1402_c30_ttiw_reg.sas, Output: t_2_1402_c30_ttiw_reg.rtf, Generated on: 02SEP2024 13:32, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	27 (27.8%)	15 (17.9%)
Censored	70 (72.2%)	69 (82.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.5 (1.5, NE)	33.8 (6.5, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	73.0% (62.7%, 80.9%)	86.5% (76.4%, 92.5%)
Month 12	73.0% (62.7%, 80.9%)	83.4% (72.5%, 90.2%)
Month 18	71.2% (60.4%, 79.5%)	81.1% (69.4%, 88.7%)
Month 24	69.0% (57.6%, 77.9%)	78.7% (66.1%, 87.1%)
Month 30	69.0% (57.6%, 77.9%)	78.7% (66.1%, 87.1%)
Month 36	69.0% (57.6%, 77.9%)	74.3% (58.8%, 84.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.55 (0.822, 2.911)	
p-value of 2-sided stratified log-rank test	0.1753	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	27	15
0	14 (51.9%)	6 (40.0%)
1	3 (11.1%)	0
2	2 (7.4%)	2 (13.3%)
3	0	3 (20.0%)
>=4	8 (29.6%)	4 (26.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	12 (12.6%)	12 (12.0%)
Censored	83 (87.4%)	88 (88.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (9.0, NE)	NE (31.3, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	86.6% (77.0%, 92.3%)	88.9% (80.3%, 93.9%)
Month 12	84.9% (74.8%, 91.2%)	88.9% (80.3%, 93.9%)
Month 18	84.9% (74.8%, 91.2%)	86.9% (77.2%, 92.6%)
Month 24	84.9% (74.8%, 91.2%)	86.9% (77.2%, 92.6%)
Month 30	84.9% (74.8%, 91.2%)	86.9% (77.2%, 92.6%)
Month 36	84.9% (74.8%, 91.2%)	81.5% (64.9%, 90.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.08 (0.484, 2.428)	
p-value of 2-sided stratified log-rank test	0.8510	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	12	12
0	3 (25.0%)	6 (50.0%)
1	2 (16.7%)	1 (8.3%)
2	2 (16.7%)	1 (8.3%)
3	0	0
>=4	5 (41.7%)	4 (33.3%)
p-value from Interaction Test[c]	0.5097	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	58 (59.8%)	48 (57.1%)
Censored	39 (40.2%)	36 (42.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	3.5 (1.5, 6.8)	9.6 (3.8, 13.2)
50%	18.7 (9.3, 28.6)	19.8 (16.1, 33.8)
75%	44.6 (32.5, NE)	NE (35.5, NE)
Survival probability (95% CI) at		
Month 6	68.0% (57.5%, 76.5%)	78.6% (67.8%, 86.1%)
Month 12	56.2% (45.3%, 65.7%)	70.8% (59.4%, 79.5%)
Month 18	51.2% (40.3%, 61.0%)	54.5% (42.7%, 64.9%)
Month 24	45.9% (35.1%, 56.1%)	44.7% (33.2%, 55.5%)
Month 30	37.8% (27.4%, 48.2%)	40.2% (29.0%, 51.2%)
Month 36	32.7% (22.5%, 43.3%)	35.7% (24.3%, 47.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.12 (0.763, 1.655)	
p-value of 2-sided stratified log-rank test	0.5562	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	58	48
0	45 (77.6%)	39 (81.3%)
1	3 (5.2%)	0
2	2 (3.4%)	2 (4.2%)
3	0	3 (6.3%)
>=4	8 (13.8%)	4 (8.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	49 (51.6%)	69 (69.0%)
Censored	46 (48.4%)	31 (31.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	9.0 (2.8, 17.4)	11.2 (8.2, 14.7)
50%	24.6 (19.2, 32.1)	20.0 (15.8, 25.8)
75%	NE (36.2, NE)	36.1 (31.3, 39.1)
Survival probability (95% CI) at		
Month 6	80.3% (70.1%, 87.3%)	86.7% (78.2%, 92.0%)
Month 12	69.9% (58.7%, 78.6%)	71.9% (61.8%, 79.8%)
Month 18	64.6% (53.1%, 74.0%)	55.9% (45.3%, 65.2%)
Month 24	52.0% (40.3%, 62.5%)	43.7% (33.5%, 53.5%)
Month 30	43.5% (32.1%, 54.3%)	36.4% (26.5%, 46.2%)
Month 36	38.6% (27.4%, 49.6%)	27.7% (18.2%, 38.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.81 (0.561, 1.172)	
p-value of 2-sided stratified log-rank test	0.2623	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	49	69
0	40 (81.6%)	63 (91.3%)
1	2 (4.1%)	1 (1.4%)
2	2 (4.1%)	1 (1.4%)
3	0	0
>=4	5 (10.2%)	4 (5.8%)
p-value from Interaction Test[c]	0.2442	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	37 (38.1%)	35 (41.7%)
Censored	60 (61.9%)	49 (58.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	6.9 (1.7, 10.4)	2.3 (1.4, 4.4)
50%	33.4 (12.5, NE)	14.6 (5.6, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	76.0% (65.9%, 83.5%)	62.1% (50.0%, 72.1%)
Month 12	62.2% (50.3%, 72.0%)	58.2% (45.7%, 68.9%)
Month 18	58.9% (46.8%, 69.1%)	49.7% (36.7%, 61.5%)
Month 24	58.9% (46.8%, 69.1%)	47.0% (33.6%, 59.2%)
Month 30	51.8% (38.8%, 63.4%)	47.0% (33.6%, 59.2%)
Month 36	48.4% (34.6%, 60.8%)	47.0% (33.6%, 59.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.27 (0.787, 2.064)	
p-value of 2-sided stratified log-rank test	0.3219	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	37	35
0	14 (37.8%)	21 (60.0%)
1	12 (32.4%)	5 (14.3%)
2	2 (5.4%)	1 (2.9%)
3	3 (8.1%)	2 (5.7%)
>=4	6 (16.2%)	6 (17.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	17 (17.9%)	25 (25.0%)
Censored	78 (82.1%)	75 (75.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (5.6, NE)	8.3 (4.2, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	84.9% (74.9%, 91.1%)	79.5% (69.5%, 86.6%)
Month 12	78.3% (66.8%, 86.2%)	69.2% (57.6%, 78.2%)
Month 18	78.3% (66.8%, 86.2%)	69.2% (57.6%, 78.2%)
Month 24	75.9% (63.7%, 84.6%)	69.2% (57.6%, 78.2%)
Month 30	75.9% (63.7%, 84.6%)	69.2% (57.6%, 78.2%)
Month 36	75.9% (63.7%, 84.6%)	69.2% (57.6%, 78.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.37 (0.738, 2.558)	
p-value of 2-sided stratified log-rank test	0.3150	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	17	25
0	8 (47.1%)	17 (68.0%)
1	5 (29.4%)	4 (16.0%)
2	1 (5.9%)	0
3	0	2 (8.0%)
>=4	3 (17.6%)	2 (8.0%)
p-value from Interaction Test[c]	0.8498	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	14 (14.4%)	8 (9.5%)
Censored	83 (85.6%)	76 (90.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (NE, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	84.7% (75.5%, 90.6%)	90.7% (81.5%, 95.5%)
Month 12	84.7% (75.5%, 90.6%)	89.1% (79.2%, 94.4%)
Month 18	84.7% (75.5%, 90.6%)	89.1% (79.2%, 94.4%)
Month 24	84.7% (75.5%, 90.6%)	89.1% (79.2%, 94.4%)
Month 30	84.7% (75.5%, 90.6%)	89.1% (79.2%, 94.4%)
Month 36	84.7% (75.5%, 90.6%)	89.1% (79.2%, 94.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.42 (0.597, 3.396)	
p-value of 2-sided stratified log-rank test	0.4191	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	14	8
0	4 (28.6%)	2 (25.0%)
1	0	0
2	3 (21.4%)	0
3	1 (7.1%)	2 (25.0%)
>=4	6 (42.9%)	4 (50.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	9 (9.5%)	10 (10.0%)
Censored	86 (90.5%)	90 (90.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (NE, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	89.0% (79.8%, 94.1%)	90.1% (81.9%, 94.7%)
Month 12	89.0% (79.8%, 94.1%)	90.1% (81.9%, 94.7%)
Month 18	89.0% (79.8%, 94.1%)	90.1% (81.9%, 94.7%)
Month 24	89.0% (79.8%, 94.1%)	90.1% (81.9%, 94.7%)
Month 30	89.0% (79.8%, 94.1%)	87.4% (76.8%, 93.4%)
Month 36	89.0% (79.8%, 94.1%)	87.4% (76.8%, 93.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.00 (0.404, 2.475)	
p-value of 2-sided stratified log-rank test	0.9961	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	9	10
0	5 (55.6%)	4 (40.0%)
1	1 (11.1%)	0
2	1 (11.1%)	2 (20.0%)
3	1 (11.1%)	0
>=4	1 (11.1%)	4 (40.0%)
p-value from Interaction Test[c]	0.5891	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	51 (52.6%)	43 (51.2%)
Censored	46 (47.4%)	41 (48.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	8.0 (5.0, 13.2)	12.6 (4.6, 16.3)
50%	28.6 (18.7, 40.6)	27.2 (17.1, 39.7)
75%	44.6 (40.6, NE)	NE (39.7, NE)
Survival probability (95% CI) at		
Month 6	79.6% (69.9%, 86.5%)	82.4% (72.1%, 89.2%)
Month 12	66.7% (55.9%, 75.5%)	75.7% (64.5%, 83.8%)
Month 18	61.7% (50.6%, 71.0%)	60.3% (48.3%, 70.4%)
Month 24	57.7% (46.5%, 67.4%)	51.5% (39.5%, 62.3%)
Month 30	46.7% (35.5%, 57.1%)	45.3% (33.5%, 56.4%)
Month 36	39.8% (28.6%, 50.8%)	40.3% (28.1%, 52.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.03 (0.684, 1.551)	
p-value of 2-sided stratified log-rank test	0.8835	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	51	43
0	41 (80.4%)	37 (86.0%)
1	0	0
2	3 (5.9%)	0
3	1 (2.0%)	2 (4.7%)
>=4	6 (11.8%)	4 (9.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	48 (50.5%)	66 (66.0%)
Censored	47 (49.5%)	34 (34.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	9.7 (3.7, 17.4)	11.8 (8.8, 15.0)
50%	24.6 (19.2, 36.2)	21.7 (17.3, 29.3)
75%	NE (37.6, NE)	36.6 (32.9, NE)
Survival probability (95% CI) at		
Month 6	82.5% (72.7%, 89.1%)	87.7% (79.4%, 92.8%)
Month 12	73.5% (62.5%, 81.7%)	73.0% (62.9%, 80.7%)
Month 18	65.6% (54.1%, 74.9%)	58.0% (47.4%, 67.2%)
Month 24	53.1% (41.4%, 63.5%)	45.8% (35.5%, 55.6%)
Month 30	44.5% (33.0%, 55.4%)	39.8% (29.7%, 49.7%)
Month 36	39.5% (28.2%, 50.6%)	31.1% (21.1%, 41.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.85 (0.586, 1.239)	
p-value of 2-sided stratified log-rank test	0.4051	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	48	66
0	44 (91.7%)	60 (90.9%)
1	1 (2.1%)	0
2	1 (2.1%)	2 (3.0%)
3	1 (2.1%)	0
>=4	1 (2.1%)	4 (6.1%)
p-value from Interaction Test[c]	0.5417	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	33 (34.0%)	33 (39.3%)
Censored	64 (66.0%)	51 (60.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	8.8 (4.2, 13.1)	3.8 (1.7, 8.6)
50%	NE (22.0, NE)	27.4 (11.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	78.4% (68.2%, 85.7%)	68.8% (56.9%, 78.1%)
Month 12	67.1% (55.6%, 76.3%)	60.6% (48.0%, 71.0%)
Month 18	62.2% (50.2%, 72.1%)	56.4% (43.4%, 67.5%)
Month 24	60.3% (48.1%, 70.5%)	51.6% (38.2%, 63.4%)
Month 30	55.9% (43.2%, 66.9%)	48.9% (35.2%, 61.2%)
Month 36	55.9% (43.2%, 66.9%)	48.9% (35.2%, 61.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.22 (0.744, 1.994)	
p-value of 2-sided stratified log-rank test	0.4340	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	33	33
0	17 (51.5%)	18 (54.5%)
1	11 (33.3%)	5 (15.2%)
2	2 (6.1%)	1 (3.0%)
3	0	0
>=4	3 (9.1%)	9 (27.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	21 (22.1%)	15 (15.0%)
Censored	74 (77.9%)	85 (85.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	7.5 (2.3, NE)	NE (8.4, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	81.1% (70.6%, 88.2%)	86.3% (77.0%, 92.0%)
Month 12	74.7% (63.0%, 83.2%)	84.7% (75.0%, 90.9%)
Month 18	72.4% (60.1%, 81.5%)	82.5% (71.8%, 89.5%)
Month 24	69.7% (56.6%, 79.6%)	79.9% (68.0%, 87.8%)
Month 30	69.7% (56.6%, 79.6%)	79.9% (68.0%, 87.8%)
Month 36	69.7% (56.6%, 79.6%)	79.9% (68.0%, 87.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.63 (0.325, 1.230)	
p-value of 2-sided stratified log-rank test	0.1735	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	21	15
0	14 (66.7%)	11 (73.3%)
1	3 (14.3%)	2 (13.3%)
2	3 (14.3%)	0
3	0	2 (13.3%)
>=4	1 (4.8%)	0
p-value from Interaction Test[c]	0.0792	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration	7 (7.2%)	8 (9.5%)
Censored	90 (92.8%)	76 (90.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (4.5, NE)	NE (2.9, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	86.3% (73.3%, 93.2%)	81.9% (67.0%, 90.6%)
Month 12	86.3% (73.3%, 93.2%)	81.9% (67.0%, 90.6%)
Month 18	86.3% (73.3%, 93.2%)	81.9% (67.0%, 90.6%)
Month 24	86.3% (73.3%, 93.2%)	81.9% (67.0%, 90.6%)
Month 30	86.3% (73.3%, 93.2%)	81.9% (67.0%, 90.6%)
Month 36	86.3% (73.3%, 93.2%)	81.9% (67.0%, 90.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.68 (0.245, 1.880)	
p-value of 2-sided stratified log-rank test	0.4523	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	7	8
0	5 (71.4%)	4 (50.0%)
1	1 (14.3%)	0
2	0	1 (12.5%)
3	0	1 (12.5%)
>=4	1 (14.3%)	2 (25.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration	6 (6.3%)	2 (2.0%)
Censored	89 (93.7%)	98 (98.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (3.0, NE)	NE (29.2, NE)
50%	NE (NE, NE)	NE (29.2, NE)
75%	NE (NE, NE)	NE (29.2, NE)
Survival probability (95% CI) at		
Month 6	86.3% (67.4%, 94.6%)	97.3% (82.3%, 99.6%)
Month 12	81.7% (61.2%, 92.1%)	97.3% (82.3%, 99.6%)
Month 18	75.9% (52.9%, 88.7%)	97.3% (82.3%, 99.6%)
Month 24	75.9% (52.9%, 88.7%)	97.3% (82.3%, 99.6%)
Month 30	75.9% (52.9%, 88.7%)	77.8% (23.2%, 95.8%)
Month 36	75.9% (52.9%, 88.7%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	2.87 (0.569, 14.432)	
p-value of 2-sided stratified log-rank test	0.1825	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	6	2
0	4 (66.7%)	2 (100%)
1	0	0
2	1 (16.7%)	0
3	0	0
>=4	1 (16.7%)	0
p-value from Interaction Test[c]	0.1279	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with deterioration or death	47 (48.5%)	43 (51.2%)
Censored	50 (51.5%)	41 (48.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	8.4 (6.0, 15.3)	8.8 (3.5, 13.2)
50%	26.3 (16.8, 31.2)	17.1 (13.3, 22.2)
75%	40.6 (32.5, NE)	35.6 (22.2, NE)
Survival probability (95% CI) at		
Month 6	84.1% (73.7%, 90.7%)	75.9% (63.2%, 84.7%)
Month 12	68.4% (56.3%, 77.8%)	69.0% (55.8%, 79.0%)
Month 18	62.3% (49.9%, 72.4%)	46.6% (33.2%, 59.0%)
Month 24	57.4% (44.8%, 68.1%)	36.5% (23.9%, 49.2%)
Month 30	40.1% (28.0%, 51.9%)	28.0% (16.6%, 40.6%)
Month 36	28.8% (17.5%, 41.2%)	22.4% (11.7%, 35.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.77 (0.502, 1.173)	
p-value of 2-sided stratified log-rank test	0.2195	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	47	43
0	45 (95.7%)	39 (90.7%)
1	1 (2.1%)	0
2	0	1 (2.3%)
3	0	1 (2.3%)
>=4	1 (2.1%)	2 (4.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with deterioration or death	45 (47.4%)	66 (66.0%)
Censored	50 (52.6%)	34 (34.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	9.5 (4.1, 13.8)	11.2 (9.4, 13.6)
50%	19.6 (13.8, 24.6)	18.1 (15.0, 22.0)
75%	30.7 (24.6, 37.6)	29.2 (22.4, 34.7)
Survival probability (95% CI) at		
Month 6	83.4% (71.3%, 90.7%)	93.6% (85.3%, 97.3%)
Month 12	71.3% (57.9%, 81.1%)	71.9% (60.2%, 80.7%)
Month 18	56.9% (43.2%, 68.5%)	50.8% (38.8%, 61.6%)
Month 24	39.5% (26.6%, 52.1%)	33.6% (23.0%, 44.6%)
Month 30	29.0% (17.4%, 41.6%)	22.7% (13.6%, 33.2%)
Month 36	19.3% (9.5%, 31.6%)	14.1% (6.9%, 23.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.99 (0.662, 1.467)	
p-value of 2-sided stratified log-rank test	0.9482	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	45	66
0	43 (95.6%)	66 (100%)
1	0	0
2	1 (2.2%)	0
3	0	0
>=4	1 (2.2%)	0
p-value from Interaction Test[c]	0.4548	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	97	84
Status [n (%)]		
Number of subjects with improvement	5 (5.2%)	6 (7.1%)
Censored	92 (94.8%)	78 (92.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (22.8, NE)	NE (5.8, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	91.7% (79.4%, 96.8%)	88.4% (73.9%, 95.1%)
Month 12	91.7% (79.4%, 96.8%)	88.4% (73.9%, 95.1%)
Month 18	91.7% (79.4%, 96.8%)	88.4% (73.9%, 95.1%)
Month 24	87.2% (69.9%, 94.9%)	81.0% (57.5%, 92.3%)
Month 30	87.2% (69.9%, 94.9%)	81.0% (57.5%, 92.3%)
Month 36	87.2% (69.9%, 94.9%)	81.0% (57.5%, 92.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Age (years): <65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.75 (0.525, 5.828)	
p-value of 2-sided stratified log-rank test	0.3565	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	5	6
0	3 (60.0%)	3 (50.0%)
1	1 (20.0%)	2 (33.3%)
2	1 (20.0%)	0
3	0	0
>=4	0	1 (16.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	95	100
Status [n (%)]		
Number of subjects with improvement	3 (3.2%)	2 (2.0%)
Censored	92 (96.8%)	98 (98.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (7.5, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	93.8% (77.3%, 98.4%)	94.1% (78.4%, 98.5%)
Month 12	89.1% (69.1%, 96.5%)	94.1% (78.4%, 98.5%)
Month 18	89.1% (69.1%, 96.5%)	94.1% (78.4%, 98.5%)
Month 24	89.1% (69.1%, 96.5%)	94.1% (78.4%, 98.5%)
Month 30	89.1% (69.1%, 96.5%)	94.1% (78.4%, 98.5%)
Month 36	89.1% (69.1%, 96.5%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2002 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Age Group (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Age (years): >=65

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.58 (0.090, 3.688)	
p-value of 2-sided stratified log-rank test	0.5564	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	3	2
0	2 (66.7%)	2 (100%)
1	0	0
2	0	0
3	0	0
>=4	1 (33.3%)	0
p-value from Interaction Test[c]	0.5366	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2002_en24_ttiw_age.sas, Output: t_2_2002_en24_ttiw_age.rtf, Generated on: 02SEP2024 13:50, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	19 (21.1%)	15 (17.2%)
Censored	71 (78.9%)	72 (82.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (2.1, NE)	NE (3.9, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	76.6% (65.7%, 84.4%)	84.7% (74.6%, 91.0%)
Month 12	76.6% (65.7%, 84.4%)	83.1% (72.6%, 89.8%)
Month 18	76.6% (65.7%, 84.4%)	78.3% (66.0%, 86.7%)
Month 24	76.6% (65.7%, 84.4%)	78.3% (66.0%, 86.7%)
Month 30	76.6% (65.7%, 84.4%)	78.3% (66.0%, 86.7%)
Month 36	76.6% (65.7%, 84.4%)	78.3% (66.0%, 86.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.27 (0.646, 2.506)	
p-value of 2-sided stratified log-rank test	0.4898	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	19	15
0	6 (31.6%)	8 (53.3%)
1	2 (10.5%)	0
2	2 (10.5%)	1 (6.7%)
3	0	2 (13.3%)
>=4	9 (47.4%)	4 (26.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	11 (31.4%)	2 (6.1%)
Censored	24 (68.6%)	31 (93.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, NE)	NE (31.3, NE)
50%	NE (3.7, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	67.9% (49.6%, 80.8%)	96.7% (78.6%, 99.5%)
Month 12	67.9% (49.6%, 80.8%)	96.7% (78.6%, 99.5%)
Month 18	67.9% (49.6%, 80.8%)	96.7% (78.6%, 99.5%)
Month 24	67.9% (49.6%, 80.8%)	96.7% (78.6%, 99.5%)
Month 30	67.9% (49.6%, 80.8%)	96.7% (78.6%, 99.5%)
Month 36	67.9% (49.6%, 80.8%)	90.6% (65.7%, 97.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	5.05 (1.117, 22.804)	
p-value of 2-sided stratified log-rank test	0.0191	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	11	2
0	7 (63.6%)	1 (50.0%)
1	0	0
2	2 (18.2%)	0
3	0	0
>=4	2 (18.2%)	1 (50.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	9 (13.4%)	10 (15.6%)
Censored	58 (86.6%)	54 (84.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (9.0, NE)	33.8 (6.9, NE)
50%	NE (NE, NE)	NE (33.8, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	89.6% (78.2%, 95.2%)	88.1% (76.5%, 94.1%)
Month 12	86.8% (73.8%, 93.6%)	86.1% (74.0%, 92.8%)
Month 18	83.3% (68.3%, 91.6%)	86.1% (74.0%, 92.8%)
Month 24	78.9% (61.4%, 89.1%)	82.3% (67.6%, 90.8%)
Month 30	78.9% (61.4%, 89.1%)	82.3% (67.6%, 90.8%)
Month 36	78.9% (61.4%, 89.1%)	72.0% (44.6%, 87.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.95 (0.384, 2.335)	
p-value of 2-sided stratified log-rank test	0.9050	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	9	10
0	4 (44.4%)	3 (30.0%)
1	3 (33.3%)	1 (10.0%)
2	0	2 (20.0%)
3	0	1 (10.0%)
>=4	2 (22.2%)	3 (30.0%)
p-value from Interaction Test[c]	0.1271	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	52 (57.8%)	59 (67.8%)
Censored	38 (42.2%)	28 (32.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	5.9 (2.2, 9.6)	9.8 (3.9, 13.2)
50%	21.1 (11.4, 32.1)	18.4 (15.8, 21.7)
75%	44.6 (32.5, NE)	37.4 (25.0, NE)
Survival probability (95% CI) at		
Month 6	72.9% (62.0%, 81.1%)	82.2% (72.3%, 88.9%)
Month 12	60.9% (49.4%, 70.6%)	71.2% (60.2%, 79.7%)
Month 18	58.1% (46.5%, 68.1%)	52.2% (40.8%, 62.4%)
Month 24	49.6% (38.0%, 60.2%)	36.5% (26.0%, 47.0%)
Month 30	41.1% (29.9%, 51.9%)	30.6% (20.7%, 41.1%)
Month 36	33.6% (22.6%, 45.0%)	28.6% (18.7%, 39.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.90 (0.618, 1.310)	
p-value of 2-sided stratified log-rank test	0.5733	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	52	59
0	39 (75.0%)	52 (88.1%)
1	2 (3.8%)	0
2	2 (3.8%)	1 (1.7%)
3	0	2 (3.4%)
>=4	9 (17.3%)	4 (6.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	19 (54.3%)	12 (36.4%)
Censored	16 (45.7%)	21 (63.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	1.4 (0.8, 22.4)	31.3 (4.6, 36.6)
50%	30.7 (3.7, NE)	39.1 (31.7, NE)
75%	NE (37.6, NE)	NE (39.1, NE)
Survival probability (95% CI) at		
Month 6	67.9% (49.6%, 80.8%)	89.6% (71.2%, 96.5%)
Month 12	67.9% (49.6%, 80.8%)	86.0% (66.9%, 94.5%)
Month 18	64.8% (46.4%, 78.3%)	78.9% (58.9%, 89.9%)
Month 24	58.0% (39.4%, 72.7%)	75.3% (55.0%, 87.4%)
Month 30	50.8% (32.3%, 66.6%)	75.3% (55.0%, 87.4%)
Month 36	43.5% (25.8%, 60.0%)	66.9% (45.8%, 81.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.64 (0.794, 3.387)	
p-value of 2-sided stratified log-rank test	0.1792	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	19	12
0	15 (78.9%)	11 (91.7%)
1	0	0
2	2 (10.5%)	0
3	0	0
>=4	2 (10.5%)	1 (8.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	36 (53.7%)	46 (71.9%)
Censored	31 (46.3%)	18 (28.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	6.8 (3.4, 9.5)	9.4 (4.2, 12.2)
50%	18.9 (9.5, 25.8)	17.2 (13.2, 24.6)
75%	NE (24.6, NE)	33.6 (25.7, NE)
Survival probability (95% CI) at		
Month 6	78.5% (65.8%, 86.9%)	81.3% (69.4%, 88.9%)
Month 12	61.9% (47.9%, 73.1%)	65.1% (51.9%, 75.5%)
Month 18	52.1% (38.2%, 64.3%)	48.3% (35.4%, 60.1%)
Month 24	41.8% (28.5%, 54.7%)	39.6% (27.3%, 51.6%)
Month 30	33.2% (20.8%, 46.2%)	29.7% (18.4%, 41.9%)
Month 36	33.2% (20.8%, 46.2%)	14.5% (4.2%, 31.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.89 (0.575, 1.381)	
p-value of 2-sided stratified log-rank test	0.6048	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	36	46
0	31 (86.1%)	39 (84.8%)
1	3 (8.3%)	1 (2.2%)
2	0	2 (4.3%)
3	0	1 (2.2%)
>=4	2 (5.6%)	3 (6.5%)
p-value from Interaction Test[c]	0.1786	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	22 (24.4%)	31 (35.6%)
Censored	68 (75.6%)	56 (64.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	11.7 (6.9, NE)	4.2 (1.6, 7.1)
50%	NE (NE, NE)	NE (10.6, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	86.3% (76.6%, 92.2%)	70.0% (58.3%, 79.0%)
Month 12	73.5% (61.4%, 82.3%)	59.0% (46.1%, 69.8%)
Month 18	73.5% (61.4%, 82.3%)	56.7% (43.6%, 67.9%)
Month 24	71.4% (58.9%, 80.7%)	53.9% (40.3%, 65.7%)
Month 30	68.8% (55.5%, 78.8%)	53.9% (40.3%, 65.7%)
Month 36	65.0% (50.1%, 76.4%)	53.9% (40.3%, 65.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.77 (1.023, 3.072)	
p-value of 2-sided stratified log-rank test	0.0392	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	22	31
0	9 (40.9%)	17 (54.8%)
1	7 (31.8%)	7 (22.6%)
2	0	0
3	2 (9.1%)	1 (3.2%)
>=4	4 (18.2%)	6 (19.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	13 (37.1%)	13 (39.4%)
Censored	22 (62.9%)	20 (60.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.1 (1.0, 28.3)	3.2 (1.4, 12.7)
50%	NE (2.8, NE)	NE (4.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	66.7% (47.9%, 80.0%)	68.2% (47.7%, 82.1%)
Month 12	62.8% (43.6%, 77.0%)	59.7% (38.8%, 75.5%)
Month 18	62.8% (43.6%, 77.0%)	51.2% (30.7%, 68.4%)
Month 24	62.8% (43.6%, 77.0%)	51.2% (30.7%, 68.4%)
Month 30	56.5% (35.5%, 73.0%)	51.2% (30.7%, 68.4%)
Month 36	56.5% (35.5%, 73.0%)	51.2% (30.7%, 68.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.05 (0.480, 2.306)	
p-value of 2-sided stratified log-rank test	0.9003	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	13	13
0	4 (30.8%)	9 (69.2%)
1	3 (23.1%)	2 (15.4%)
2	3 (23.1%)	0
3	1 (7.7%)	1 (7.7%)
>=4	2 (15.4%)	1 (7.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	19 (28.4%)	16 (25.0%)
Censored	48 (71.6%)	48 (75.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	8.3 (1.5, 13.1)	8.3 (1.6, NE)
50%	NE (12.5, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	78.9% (65.7%, 87.5%)	75.8% (62.5%, 84.9%)
Month 12	67.8% (52.1%, 79.4%)	73.7% (60.1%, 83.3%)
Month 18	61.4% (44.7%, 74.4%)	70.6% (56.1%, 81.1%)
Month 24	61.4% (44.7%, 74.4%)	70.6% (56.1%, 81.1%)
Month 30	56.2% (38.0%, 71.0%)	70.6% (56.1%, 81.1%)
Month 36	56.2% (38.0%, 71.0%)	70.6% (56.1%, 81.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.75 (0.387, 1.469)	
p-value of 2-sided stratified log-rank test	0.4014	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	19	16
0	9 (47.4%)	12 (75.0%)
1	7 (36.8%)	0
2	0	1 (6.3%)
3	0	2 (12.5%)
>=4	3 (15.8%)	1 (6.3%)
p-value from Interaction Test[c]	0.1646	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	12 (13.3%)	9 (10.3%)
Censored	78 (86.7%)	78 (89.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (NE, NE)	NE (26.2, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	85.5% (75.8%, 91.5%)	91.1% (82.2%, 95.6%)
Month 12	85.5% (75.8%, 91.5%)	89.5% (80.0%, 94.6%)
Month 18	85.5% (75.8%, 91.5%)	89.5% (80.0%, 94.6%)
Month 24	85.5% (75.8%, 91.5%)	89.5% (80.0%, 94.6%)
Month 30	85.5% (75.8%, 91.5%)	85.6% (72.0%, 92.9%)
Month 36	85.5% (75.8%, 91.5%)	85.6% (72.0%, 92.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.33 (0.560, 3.157)	
p-value of 2-sided stratified log-rank test	0.5162	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	12	9
0	3 (25.0%)	4 (44.4%)
1	1 (8.3%)	0
2	1 (8.3%)	2 (22.2%)
3	1 (8.3%)	0
>=4	6 (50.0%)	3 (33.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	7 (20.0%)	0
Censored	28 (80.0%)	33 (100%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (1.3, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	79.4% (61.6%, 89.6%)	100% (100%, 100%)
Month 12	79.4% (61.6%, 89.6%)	100% (100%, 100%)
Month 18	79.4% (61.6%, 89.6%)	100% (100%, 100%)
Month 24	79.4% (61.6%, 89.6%)	100% (100%, 100%)
Month 30	79.4% (61.6%, 89.6%)	100% (100%, 100%)
Month 36	79.4% (61.6%, 89.6%)	100% (100%, 100%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	- (-, -)	
p-value of 2-sided stratified log-rank test	0.0153	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	7	0
0	4 (57.1%)	0
1	0	0
2	2 (28.6%)	0
3	1 (14.3%)	0
>=4	0	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	4 (6.0%)	9 (14.1%)
Censored	63 (94.0%)	55 (85.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (NE, NE)	NE (4.2, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	93.0% (82.4%, 97.3%)	84.8% (72.8%, 91.8%)
Month 12	93.0% (82.4%, 97.3%)	84.8% (72.8%, 91.8%)
Month 18	93.0% (82.4%, 97.3%)	84.8% (72.8%, 91.8%)
Month 24	93.0% (82.4%, 97.3%)	84.8% (72.8%, 91.8%)
Month 30	93.0% (82.4%, 97.3%)	84.8% (72.8%, 91.8%)
Month 36	93.0% (82.4%, 97.3%)	84.8% (72.8%, 91.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.45 (0.138, 1.456)	
p-value of 2-sided stratified log-rank test	0.1706	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	4	9
0	2 (50.0%)	2 (22.2%)
1	0	0
2	1 (25.0%)	0
3	0	2 (22.2%)
>=4	1 (25.0%)	5 (55.6%)
p-value from Interaction Test[c]	0.3227	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	49 (54.4%)	54 (62.1%)
Censored	41 (45.6%)	33 (37.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	8.0 (2.9, 14.9)	12.6 (8.2, 16.0)
50%	26.3 (18.2, 32.6)	20.0 (16.7, 26.1)
75%	44.6 (36.2, NE)	39.7 (29.3, NE)
Survival probability (95% CI) at		
Month 6	81.2% (71.1%, 88.0%)	88.1% (79.1%, 93.4%)
Month 12	68.1% (56.7%, 77.1%)	76.8% (66.1%, 84.5%)
Month 18	62.6% (50.9%, 72.3%)	57.4% (45.8%, 67.4%)
Month 24	54.1% (42.2%, 64.5%)	41.2% (30.1%, 51.9%)
Month 30	45.5% (33.9%, 56.3%)	35.3% (24.7%, 46.1%)
Month 36	36.4% (25.0%, 47.8%)	33.3% (22.7%, 44.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.91 (0.620, 1.349)	
p-value of 2-sided stratified log-rank test	0.6507	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	49	54
0	40 (81.6%)	49 (90.7%)
1	1 (2.0%)	0
2	1 (2.0%)	2 (3.7%)
3	1 (2.0%)	0
>=4	6 (12.2%)	3 (5.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	16 (45.7%)	11 (33.3%)
Censored	19 (54.3%)	22 (66.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	20.3 (1.3, 28.6)	31.7 (4.6, 36.6)
50%	37.6 (25.0, NE)	39.1 (34.7, NE)
75%	NE (37.6, NE)	NE (39.1, NE)
Survival probability (95% CI) at		
Month 6	79.4% (61.6%, 89.6%)	93.0% (74.7%, 98.2%)
Month 12	79.4% (61.6%, 89.6%)	89.4% (70.6%, 96.5%)
Month 18	76.2% (58.0%, 87.4%)	82.2% (62.5%, 92.2%)
Month 24	69.3% (50.3%, 82.3%)	78.7% (58.6%, 89.8%)
Month 30	58.4% (38.9%, 73.5%)	78.7% (58.6%, 89.8%)
Month 36	50.8% (31.7%, 67.1%)	69.0% (46.8%, 83.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.39 (0.645, 3.010)	
p-value of 2-sided stratified log-rank test	0.3974	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	16	11
0	13 (81.3%)	11 (100%)
1	0	0
2	2 (12.5%)	0
3	1 (6.3%)	0
>=4	0	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	34 (50.7%)	44 (68.8%)
Censored	33 (49.3%)	20 (31.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	8.3 (4.9, 13.2)	9.0 (2.3, 11.8)
50%	23.2 (13.2, 40.6)	19.0 (12.2, 27.2)
75%	NE (29.8, NE)	35.5 (27.2, NE)
Survival probability (95% CI) at		
Month 6	81.8% (69.5%, 89.5%)	78.1% (65.9%, 86.4%)
Month 12	67.1% (53.3%, 77.7%)	63.5% (50.4%, 74.1%)
Month 18	57.4% (43.4%, 69.2%)	50.1% (37.1%, 61.8%)
Month 24	49.1% (35.1%, 61.6%)	42.9% (30.2%, 54.9%)
Month 30	37.8% (24.5%, 51.0%)	33.0% (21.2%, 45.3%)
Month 36	37.8% (24.5%, 51.0%)	16.9% (5.8%, 32.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.80 (0.512, 1.259)	
p-value of 2-sided stratified log-rank test	0.3401	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	34	44
0	32 (94.1%)	37 (84.1%)
1	0	0
2	1 (2.9%)	0
3	0	2 (4.5%)
>=4	1 (2.9%)	5 (11.4%)
p-value from Interaction Test[c]	0.3420	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	21 (23.3%)	22 (25.3%)
Censored	69 (76.7%)	65 (74.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	14.3 (6.2, NE)	6.5 (2.3, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	86.3% (76.5%, 92.2%)	76.3% (64.9%, 84.4%)
Month 12	75.6% (64.0%, 84.0%)	71.4% (59.3%, 80.4%)
Month 18	73.9% (61.9%, 82.6%)	71.4% (59.3%, 80.4%)
Month 24	71.8% (59.3%, 81.0%)	68.5% (55.5%, 78.4%)
Month 30	68.8% (55.3%, 78.9%)	68.5% (55.5%, 78.4%)
Month 36	68.8% (55.3%, 78.9%)	68.5% (55.5%, 78.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.17 (0.644, 2.136)	
p-value of 2-sided stratified log-rank test	0.6055	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	21	22
0	11 (52.4%)	13 (59.1%)
1	7 (33.3%)	6 (27.3%)
2	2 (9.5%)	0
3	0	0
>=4	1 (4.8%)	3 (13.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	14 (40.0%)	12 (36.4%)
Censored	21 (60.0%)	21 (63.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	2.3 (1.5, 15.3)	5.5 (1.6, 14.1)
50%	NE (6.7, NE)	NE (11.1, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	69.5% (50.7%, 82.3%)	71.4% (50.7%, 84.6%)
Month 12	62.2% (42.8%, 76.6%)	62.5% (41.0%, 78.0%)
Month 18	57.4% (37.4%, 73.1%)	58.0% (36.6%, 74.5%)
Month 24	57.4% (37.4%, 73.1%)	53.6% (32.4%, 70.8%)
Month 30	51.6% (31.0%, 68.9%)	53.6% (32.4%, 70.8%)
Month 36	51.6% (31.0%, 68.9%)	53.6% (32.4%, 70.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.90 (0.409, 1.985)	
p-value of 2-sided stratified log-rank test	0.7975	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	14	12
0	7 (50.0%)	9 (75.0%)
1	3 (21.4%)	0
2	1 (7.1%)	0
3	0	1 (8.3%)
>=4	3 (21.4%)	2 (16.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	19 (28.4%)	14 (21.9%)
Censored	48 (71.6%)	50 (78.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	8.8 (3.0, 16.8)	21.4 (3.6, NE)
50%	NE (13.1, NE)	NE (27.4, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	75.6% (61.5%, 85.1%)	84.6% (72.5%, 91.7%)
Month 12	67.3% (51.6%, 78.9%)	82.4% (69.6%, 90.2%)
Month 18	60.5% (43.5%, 73.7%)	75.4% (59.3%, 85.8%)
Month 24	56.1% (38.4%, 70.6%)	71.2% (53.5%, 83.1%)
Month 30	56.1% (38.4%, 70.6%)	66.1% (46.7%, 79.9%)
Month 36	56.1% (38.4%, 70.6%)	66.1% (46.7%, 79.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.64 (0.322, 1.283)	
p-value of 2-sided stratified log-rank test	0.2040	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	19	14
0	13 (68.4%)	7 (50.0%)
1	4 (21.1%)	1 (7.1%)
2	2 (10.5%)	1 (7.1%)
3	0	1 (7.1%)
>=4	0	4 (28.6%)
p-value from Interaction Test[c]	0.4664	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration	7 (7.8%)	8 (9.2%)
Censored	83 (92.2%)	79 (90.8%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (2.2, NE)	29.2 (1.7, NE)
50%	NE (NE, NE)	NE (29.2, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	83.9% (69.1%, 92.0%)	79.9% (62.1%, 89.9%)
Month 12	83.9% (69.1%, 92.0%)	79.9% (62.1%, 89.9%)
Month 18	83.9% (69.1%, 92.0%)	79.9% (62.1%, 89.9%)
Month 24	83.9% (69.1%, 92.0%)	79.9% (62.1%, 89.9%)
Month 30	83.9% (69.1%, 92.0%)	66.5% (34.1%, 85.7%)
Month 36	83.9% (69.1%, 92.0%)	66.5% (34.1%, 85.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.68 (0.239, 1.904)	
p-value of 2-sided stratified log-rank test	0.4545	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	7	8
0	5 (71.4%)	5 (62.5%)
1	1 (14.3%)	0
2	0	0
3	0	1 (12.5%)
>=4	1 (14.3%)	2 (25.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
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Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration	3 (8.6%)	0
Censored	32 (91.4%)	33 (100%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (0.7, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	82.1% (53.9%, 93.9%)	100% (100%, 100%)
Month 12	82.1% (53.9%, 93.9%)	100% (100%, 100%)
Month 18	82.1% (53.9%, 93.9%)	100% (100%, 100%)
Month 24	82.1% (53.9%, 93.9%)	100% (100%, 100%)
Month 30	82.1% (53.9%, 93.9%)	100% (100%, 100%)
Month 36	82.1% (53.9%, 93.9%)	100% (100%, 100%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	- (-, -)	
p-value of 2-sided stratified log-rank test	0.0758	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	3	0
0	1 (33.3%)	0
1	0	0
2	1 (33.3%)	0
3	0	0
>=4	1 (33.3%)	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration	3 (4.5%)	2 (3.1%)
Censored	64 (95.5%)	62 (96.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (4.5, NE)	NE (2.9, NE)
50%	NE (17.1, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	95.0% (69.5%, 99.3%)	91.7% (70.5%, 97.9%)
Month 12	89.4% (63.8%, 97.3%)	91.7% (70.5%, 97.9%)
Month 18	80.5% (48.9%, 93.6%)	91.7% (70.5%, 97.9%)
Month 24	80.5% (48.9%, 93.6%)	91.7% (70.5%, 97.9%)
Month 30	80.5% (48.9%, 93.6%)	91.7% (70.5%, 97.9%)
Month 36	80.5% (48.9%, 93.6%)	91.7% (70.5%, 97.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.41 (0.234, 8.438)	
p-value of 2-sided stratified log-rank test	0.7082	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	3	2
0	3 (100%)	1 (50.0%)
1	0	0
2	0	1 (50.0%)
3	0	0
>=4	0	0
p-value from Interaction Test[c]	0.7292	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with deterioration or death	44 (48.9%)	56 (64.4%)
Censored	46 (51.1%)	31 (35.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	9.6 (5.9, 17.4)	9.8 (5.4, 12.9)
50%	24.6 (18.2, 30.2)	16.7 (13.2, 18.7)
75%	36.2 (30.2, NE)	23.1 (18.8, 32.4)
Survival probability (95% CI) at		
Month 6	83.8% (72.6%, 90.7%)	83.2% (71.6%, 90.3%)
Month 12	70.8% (58.0%, 80.3%)	68.5% (55.5%, 78.4%)
Month 18	63.8% (50.6%, 74.4%)	44.5% (31.8%, 56.5%)
Month 24	53.0% (39.6%, 64.7%)	24.0% (14.0%, 35.4%)
Month 30	37.6% (25.1%, 50.1%)	15.4% (7.6%, 25.7%)
Month 36	25.3% (14.0%, 38.2%)	13.2% (6.0%, 23.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.60 (0.397, 0.896)	
p-value of 2-sided stratified log-rank test	0.0121	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	44	56
0	42 (95.5%)	53 (94.6%)
1	1 (2.3%)	0
2	0	0
3	0	1 (1.8%)
>=4	1 (2.3%)	2 (3.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with deterioration or death	15 (42.9%)	11 (33.3%)
Censored	20 (57.1%)	22 (66.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	13.2 (0.7, 27.6)	13.6 (3.8, 34.7)
50%	28.6 (20.3, 37.6)	36.1 (13.6, NE)
75%	NE (30.7, NE)	NE (36.1, NE)
Survival probability (95% CI) at		
Month 6	87.1% (65.2%, 95.7%)	90.7% (67.6%, 97.6%)
Month 12	82.8% (60.3%, 93.2%)	85.6% (61.7%, 95.1%)
Month 18	74.1% (51.1%, 87.4%)	74.9% (49.7%, 88.8%)
Month 24	64.5% (41.2%, 80.5%)	69.2% (43.5%, 84.9%)
Month 30	49.6% (27.4%, 68.4%)	69.2% (43.5%, 84.9%)
Month 36	34.0% (15.0%, 54.2%)	54.5% (28.1%, 74.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.36 (0.619, 2.968)	
p-value of 2-sided stratified log-rank test	0.4459	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	15	11
0	13 (86.7%)	11 (100%)
1	0	0
2	1 (6.7%)	0
3	0	0
>=4	1 (6.7%)	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with deterioration or death	33 (49.3%)	42 (65.6%)
Censored	34 (50.7%)	22 (34.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	8.3 (4.9, 9.6)	10.2 (4.7, 13.2)
50%	15.3 (9.5, 23.2)	16.1 (13.2, 22.1)
75%	29.8 (19.5, NE)	28.2 (22.0, 35.5)
Survival probability (95% CI) at		
Month 6	82.4% (67.9%, 90.8%)	86.8% (74.3%, 93.5%)
Month 12	61.4% (45.3%, 74.0%)	67.1% (52.5%, 78.1%)
Month 18	46.4% (30.9%, 60.5%)	44.5% (30.4%, 57.6%)
Month 24	35.2% (20.9%, 49.9%)	35.3% (22.2%, 48.7%)
Month 30	22.2% (10.1%, 37.1%)	20.7% (10.3%, 33.7%)
Month 36	17.7% (6.8%, 32.9%)	8.9% (2.4%, 20.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.00 (0.634, 1.581)	
p-value of 2-sided stratified log-rank test	0.9968	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	33	42
0	33 (100%)	41 (97.6%)
1	0	0
2	0	1 (2.4%)
3	0	0
>=4	0	0
p-value from Interaction Test[c]	0.1240	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	90	87
Status [n (%)]		
Number of subjects with improvement	4 (4.4%)	7 (8.0%)
Censored	86 (95.6%)	80 (92.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (22.8, NE)	22.6 (2.3, NE)
50%	NE (NE, NE)	NE (22.6, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	95.1% (81.8%, 98.8%)	81.6% (62.4%, 91.6%)
Month 12	91.8% (76.4%, 97.3%)	81.6% (62.4%, 91.6%)
Month 18	91.8% (76.4%, 97.3%)	81.6% (62.4%, 91.6%)
Month 24	86.1% (64.7%, 95.0%)	72.5% (45.6%, 87.7%)
Month 30	86.1% (64.7%, 95.0%)	72.5% (45.6%, 87.7%)
Month 36	86.1% (64.7%, 95.0%)	72.5% (45.6%, 87.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Disease Status: Recurrent

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	2.84 (0.818, 9.836)	
p-value of 2-sided stratified log-rank test	0.0865	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	4	7
0	4 (100%)	4 (57.1%)
1	0	2 (28.6%)
2	0	0
3	0	0
>=4	0	1 (14.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	35	33
Status [n (%)]		
Number of subjects with improvement	1 (2.9%)	0
Censored	34 (97.1%)	33 (100%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (0.8, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	94.7% (68.1%, 99.2%)	100% (100%, 100%)
Month 12	94.7% (68.1%, 99.2%)	100% (100%, 100%)
Month 18	94.7% (68.1%, 99.2%)	100% (100%, 100%)
Month 24	94.7% (68.1%, 99.2%)	100% (100%, 100%)
Month 30	94.7% (68.1%, 99.2%)	100% (100%, 100%)
Month 36	94.7% (68.1%, 99.2%)	100% (100%, 100%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Disease Status: Primary Stage III

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	- (-, -)	
p-value of 2-sided stratified log-rank test	0.3304	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	1	0
0	0	0
1	1 (100%)	0
2	0	0
3	0	0
>=4	0	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	67	64
Status [n (%)]		
Number of subjects with improvement	3 (4.5%)	1 (1.6%)
Censored	64 (95.5%)	63 (98.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (0.8, NE)	NE (1.4, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	85.9% (62.4%, 95.2%)	96.0% (74.8%, 99.4%)
Month 12	85.9% (62.4%, 95.2%)	96.0% (74.8%, 99.4%)
Month 18	85.9% (62.4%, 95.2%)	96.0% (74.8%, 99.4%)
Month 24	85.9% (62.4%, 95.2%)	96.0% (74.8%, 99.4%)
Month 30	85.9% (62.4%, 95.2%)	96.0% (74.8%, 99.4%)
Month 36	85.9% (62.4%, 95.2%)	96.0% (74.8%, 99.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2202 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Disease Status (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Disease Status: Primary Stage IV

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.28 (0.029, 2.702)	
p-value of 2-sided stratified log-rank test	0.2402	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	3	1
0	1 (33.3%)	1 (100%)
1	0	0
2	1 (33.3%)	0
3	0	0
>=4	1 (33.3%)	0
p-value from Interaction Test[c]	0.2233	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2202_en24_ttiw_dstat.sas, Output: t_2_2202_en24_ttiw_dstat.rtf, Generated on: 02SEP2024 13:53, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	29 (21.5%)	23 (16.8%)
Censored	106 (78.5%)	114 (83.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (2.8, NE)	NE (16.1, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	78.0% (69.5%, 84.4%)	86.2% (78.8%, 91.2%)
Month 12	76.9% (68.3%, 83.5%)	84.3% (76.4%, 89.7%)
Month 18	76.9% (68.3%, 83.5%)	82.9% (74.6%, 88.7%)
Month 24	75.4% (66.3%, 82.4%)	81.5% (72.7%, 87.7%)
Month 30	75.4% (66.3%, 82.4%)	81.5% (72.7%, 87.7%)
Month 36	75.4% (66.3%, 82.4%)	75.7% (63.4%, 84.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.31 (0.758, 2.272)	
p-value of 2-sided stratified log-rank test	0.3329	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	29	23
0	14 (48.3%)	11 (47.8%)
1	5 (17.2%)	1 (4.3%)
2	3 (10.3%)	3 (13.0%)
3	0	2 (8.7%)
>=4	7 (24.1%)	6 (26.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	10 (17.5%)	4 (8.5%)
Censored	47 (82.5%)	43 (91.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (0.8, NE)	NE (15.8, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	82.6% (69.1%, 90.5%)	92.8% (79.3%, 97.6%)
Month 12	82.6% (69.1%, 90.5%)	92.8% (79.3%, 97.6%)
Month 18	78.8% (63.3%, 88.3%)	88.2% (69.9%, 95.7%)
Month 24	78.8% (63.3%, 88.3%)	88.2% (69.9%, 95.7%)
Month 30	78.8% (63.3%, 88.3%)	88.2% (69.9%, 95.7%)
Month 36	78.8% (63.3%, 88.3%)	88.2% (69.9%, 95.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	2.04 (0.634, 6.578)	
p-value of 2-sided stratified log-rank test	0.2185	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	10	4
0	3 (30.0%)	1 (25.0%)
1	0	0
2	1 (10.0%)	0
3	0	1 (25.0%)
>=4	6 (60.0%)	2 (50.0%)
p-value from Interaction Test[c]	0.4098	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	69 (51.1%)	90 (65.7%)
Censored	66 (48.9%)	47 (34.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	8.0 (2.8, 11.0)	9.8 (5.0, 12.6)
50%	25.8 (19.6, 36.2)	18.7 (16.0, 25.7)
75%	44.6 (NE, NE)	39.1 (33.8, NE)
Survival probability (95% CI) at		
Month 6	76.2% (67.8%, 82.7%)	81.2% (73.5%, 86.9%)
Month 12	67.4% (58.2%, 74.9%)	69.5% (60.8%, 76.6%)
Month 18	63.6% (54.3%, 71.6%)	52.9% (43.9%, 61.1%)
Month 24	52.7% (43.1%, 61.5%)	43.1% (34.4%, 51.5%)
Month 30	46.5% (36.9%, 55.6%)	36.2% (27.8%, 44.6%)
Month 36	40.9% (31.4%, 50.2%)	31.4% (23.1%, 40.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.79 (0.579, 1.088)	
p-value of 2-sided stratified log-rank test	0.1497	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	69	90
0	54 (78.3%)	78 (86.7%)
1	5 (7.2%)	1 (1.1%)
2	3 (4.3%)	3 (3.3%)
3	0	2 (2.2%)
>=4	7 (10.1%)	6 (6.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	38 (66.7%)	27 (57.4%)
Censored	19 (33.3%)	20 (42.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	4.9 (1.1, 6.8)	12.8 (6.0, 18.2)
50%	13.2 (6.2, 24.6)	22.1 (16.7, 32.9)
75%	34.1 (24.3, NE)	36.5 (32.4, NE)
Survival probability (95% CI) at		
Month 6	68.4% (54.1%, 79.1%)	88.7% (75.0%, 95.1%)
Month 12	52.0% (37.6%, 64.6%)	77.1% (61.6%, 87.0%)
Month 18	43.7% (29.8%, 56.8%)	62.4% (46.1%, 75.1%)
Month 24	39.5% (26.1%, 52.7%)	47.2% (31.4%, 61.4%)
Month 30	26.9% (15.4%, 39.7%)	44.4% (28.9%, 58.9%)
Month 36	22.4% (10.9%, 36.4%)	32.1% (16.9%, 48.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.52 (0.914, 2.513)	
p-value of 2-sided stratified log-rank test	0.1040	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	38	27
0	31 (81.6%)	24 (88.9%)
1	0	0
2	1 (2.6%)	0
3	0	1 (3.7%)
>=4	6 (15.8%)	2 (7.4%)
p-value from Interaction Test[c]	0.0263	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	43 (31.9%)	48 (35.0%)
Censored	92 (68.1%)	89 (65.0%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	7.2 (1.6, 12.5)	4.3 (2.1, 8.4)
50%	NE (28.3, NE)	NE (13.0, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	77.2% (68.7%, 83.7%)	69.7% (60.6%, 77.0%)
Month 12	67.8% (58.1%, 75.6%)	63.1% (53.4%, 71.3%)
Month 18	65.4% (55.6%, 73.6%)	57.9% (47.7%, 66.8%)
Month 24	63.9% (53.8%, 72.3%)	56.3% (46.0%, 65.5%)
Month 30	60.4% (49.7%, 69.5%)	56.3% (46.0%, 65.5%)
Month 36	58.2% (46.9%, 67.8%)	56.3% (46.0%, 65.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.15 (0.756, 1.746)	
p-value of 2-sided stratified log-rank test	0.5165	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	43	48
0	19 (44.2%)	31 (64.6%)
1	12 (27.9%)	8 (16.7%)
2	3 (7.0%)	0
3	2 (4.7%)	2 (4.2%)
>=4	7 (16.3%)	7 (14.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	11 (19.3%)	12 (25.5%)
Censored	46 (80.7%)	35 (74.5%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	10.4 (5.5, NE)	8.3 (1.5, NE)
50%	NE (26.2, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	87.1% (73.3%, 94.0%)	78.1% (62.1%, 87.9%)
Month 12	73.9% (56.1%, 85.4%)	68.1% (50.2%, 80.8%)
Month 18	73.9% (56.1%, 85.4%)	68.1% (50.2%, 80.8%)
Month 24	73.9% (56.1%, 85.4%)	68.1% (50.2%, 80.8%)
Month 30	68.2% (47.8%, 82.0%)	68.1% (50.2%, 80.8%)
Month 36	NE (NE, NE)	68.1% (50.2%, 80.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Interest Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.37 (0.579, 3.241)	
p-value of 2-sided stratified log-rank test	0.4728	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	11	12
0	3 (27.3%)	7 (58.3%)
1	5 (45.5%)	1 (8.3%)
2	0	1 (8.3%)
3	1 (9.1%)	2 (16.7%)
>=4	2 (18.2%)	1 (8.3%)
p-value from Interaction Test[c]	0.6864	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	16 (11.9%)	15 (10.9%)
Censored	119 (88.1%)	122 (89.1%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (NE, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	86.9% (79.4%, 91.8%)	89.7% (82.8%, 93.9%)
Month 12	86.9% (79.4%, 91.8%)	88.7% (81.6%, 93.1%)
Month 18	86.9% (79.4%, 91.8%)	88.7% (81.6%, 93.1%)
Month 24	86.9% (79.4%, 91.8%)	88.7% (81.6%, 93.1%)
Month 30	86.9% (79.4%, 91.8%)	86.9% (78.7%, 92.1%)
Month 36	86.9% (79.4%, 91.8%)	86.9% (78.7%, 92.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.07 (0.529, 2.174)	
p-value of 2-sided stratified log-rank test	0.8407	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	16	15
0	6 (37.5%)	5 (33.3%)
1	1 (6.3%)	0
2	3 (18.8%)	2 (13.3%)
3	1 (6.3%)	1 (6.7%)
>=4	5 (31.3%)	7 (46.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	7 (12.3%)	3 (6.4%)
Censored	50 (87.7%)	44 (93.6%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (1.7, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	86.4% (73.6%, 93.3%)	92.7% (79.0%, 97.6%)
Month 12	86.4% (73.6%, 93.3%)	92.7% (79.0%, 97.6%)
Month 18	86.4% (73.6%, 93.3%)	92.7% (79.0%, 97.6%)
Month 24	86.4% (73.6%, 93.3%)	92.7% (79.0%, 97.6%)
Month 30	86.4% (73.6%, 93.3%)	92.7% (79.0%, 97.6%)
Month 36	86.4% (73.6%, 93.3%)	92.7% (79.0%, 97.6%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.87 (0.478, 7.295)	
p-value of 2-sided stratified log-rank test	0.3605	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	7	3
0	3 (42.9%)	1 (33.3%)
1	0	0
2	1 (14.3%)	0
3	1 (14.3%)	1 (33.3%)
>=4	2 (28.6%)	1 (33.3%)
p-value from Interaction Test[c]	0.4140	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	61 (45.2%)	83 (60.6%)
Censored	74 (54.8%)	54 (39.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	13.8 (8.3, 20.1)	11.2 (8.2, 13.5)
50%	32.1 (25.0, NE)	21.7 (17.2, 29.8)
75%	44.6 (NE, NE)	NE (36.6, NE)
Survival probability (95% CI) at		
Month 6	84.9% (77.4%, 90.1%)	84.2% (76.9%, 89.4%)
Month 12	77.0% (68.4%, 83.5%)	73.1% (64.6%, 79.9%)
Month 18	72.3% (63.3%, 79.5%)	57.0% (47.9%, 65.1%)
Month 24	62.3% (52.6%, 70.6%)	47.8% (38.8%, 56.3%)
Month 30	54.0% (44.1%, 62.9%)	40.8% (32.0%, 49.4%)
Month 36	47.1% (37.1%, 56.5%)	35.5% (26.6%, 44.5%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.72 (0.513, 0.997)	
p-value of 2-sided stratified log-rank test	0.0478	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	61	83
0	51 (83.6%)	73 (88.0%)
1	1 (1.6%)	0
2	3 (4.9%)	2 (2.4%)
3	1 (1.6%)	1 (1.2%)
>=4	5 (8.2%)	7 (8.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	38 (66.7%)	26 (55.3%)
Censored	19 (33.3%)	21 (44.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	5.3 (1.7, 7.5)	12.8 (4.1, 18.5)
50%	13.2 (7.0, 24.6)	22.4 (17.3, 36.5)
75%	34.1 (24.3, NE)	36.5 (32.4, NE)
Survival probability (95% CI) at		
Month 6	71.8% (57.6%, 82.0%)	88.7% (74.9%, 95.1%)
Month 12	53.6% (39.1%, 66.1%)	77.1% (61.5%, 87.0%)
Month 18	43.3% (29.4%, 56.4%)	64.9% (48.6%, 77.2%)
Month 24	39.2% (25.8%, 52.3%)	49.4% (33.4%, 63.6%)
Month 30	26.3% (14.9%, 39.2%)	46.7% (30.8%, 61.1%)
Month 36	21.9% (10.6%, 35.9%)	33.7% (17.9%, 50.3%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.58 (0.950, 2.641)	
p-value of 2-sided stratified log-rank test	0.0755	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	38	26
0	34 (89.5%)	24 (92.3%)
1	0	0
2	1 (2.6%)	0
3	1 (2.6%)	1 (3.8%)
>=4	2 (5.3%)	1 (3.8%)
p-value from Interaction Test[c]	0.0089	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	44 (32.6%)	38 (27.7%)
Censored	91 (67.4%)	99 (72.3%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	6.9 (3.5, 13.1)	8.4 (4.2, 22.1)
50%	NE (22.0, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	77.3% (68.6%, 83.8%)	77.0% (68.4%, 83.5%)
Month 12	67.2% (57.6%, 75.2%)	71.7% (62.4%, 79.1%)
Month 18	62.1% (51.9%, 70.8%)	68.9% (59.1%, 76.8%)
Month 24	59.1% (48.5%, 68.2%)	65.6% (55.2%, 74.2%)
Month 30	57.3% (46.5%, 66.7%)	63.7% (52.8%, 72.7%)
Month 36	57.3% (46.5%, 66.7%)	63.7% (52.8%, 72.7%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	0.84 (0.542, 1.303)	
p-value of 2-sided stratified log-rank test	0.4302	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	44	38
0	26 (59.1%)	24 (63.2%)
1	11 (25.0%)	4 (10.5%)
2	4 (9.1%)	1 (2.6%)
3	0	1 (2.6%)
>=4	3 (6.8%)	8 (21.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	10 (17.5%)	10 (21.3%)
Censored	47 (82.5%)	37 (78.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	26.2 (4.2, NE)	16.6 (2.4, NE)
50%	NE (NE, NE)	NE (21.4, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	85.6% (72.1%, 92.9%)	82.6% (67.0%, 91.3%)
Month 12	79.5% (63.7%, 89.0%)	79.0% (62.1%, 89.1%)
Month 18	79.5% (63.7%, 89.0%)	74.1% (54.8%, 86.1%)
Month 24	79.5% (63.7%, 89.0%)	68.8% (47.8%, 82.8%)
Month 30	73.4% (53.2%, 85.9%)	68.8% (47.8%, 82.8%)
Month 36	NE (NE, NE)	68.8% (47.8%, 82.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Activity Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.13 (0.454, 2.831)	
p-value of 2-sided stratified log-rank test	0.7876	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	10	10
0	5 (50.0%)	5 (50.0%)
1	3 (30.0%)	3 (30.0%)
2	1 (10.0%)	0
3	0	1 (10.0%)
>=4	1 (10.0%)	1 (10.0%)
p-value from Interaction Test[c]	0.4984	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration	9 (6.7%)	8 (5.8%)
Censored	126 (93.3%)	129 (94.2%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (9.5, NE)	NE (29.2, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	88.1% (76.6%, 94.2%)	88.3% (76.9%, 94.3%)
Month 12	86.1% (74.0%, 92.8%)	88.3% (76.9%, 94.3%)
Month 18	83.3% (70.0%, 91.1%)	88.3% (76.9%, 94.3%)
Month 24	83.3% (70.0%, 91.1%)	88.3% (76.9%, 94.3%)
Month 30	83.3% (70.0%, 91.1%)	80.9% (58.9%, 91.9%)
Month 36	83.3% (70.0%, 91.1%)	80.9% (58.9%, 91.9%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.95 (0.360, 2.488)	
p-value of 2-sided stratified log-rank test	0.9113	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	9	8
0	7 (77.8%)	5 (62.5%)
1	0	0
2	1 (11.1%)	0
3	0	1 (12.5%)
>=4	1 (11.1%)	2 (25.0%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration	4 (7.0%)	2 (4.3%)
Censored	53 (93.0%)	45 (95.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (0.7, NE)	NE (1.7, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	81.0% (56.7%, 92.4%)	88.8% (62.1%, 97.1%)
Month 12	81.0% (56.7%, 92.4%)	88.8% (62.1%, 97.1%)
Month 18	81.0% (56.7%, 92.4%)	88.8% (62.1%, 97.1%)
Month 24	81.0% (56.7%, 92.4%)	88.8% (62.1%, 97.1%)
Month 30	81.0% (56.7%, 92.4%)	88.8% (62.1%, 97.1%)
Month 36	81.0% (56.7%, 92.4%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.83 (0.319, 10.489)	
p-value of 2-sided stratified log-rank test	0.4928	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	4	2
0	2 (50.0%)	1 (50.0%)
1	1 (25.0%)	0
2	0	1 (50.0%)
3	0	0
>=4	1 (25.0%)	0
p-value from Interaction Test[c]	0.5958	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with deterioration or death	55 (40.7%)	83 (60.6%)
Censored	80 (59.3%)	54 (39.4%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	13.8 (8.4, 19.5)	10.2 (8.2, 12.6)
50%	26.3 (20.3, 31.2)	17.2 (14.7, 21.5)
75%	40.6 (32.5, NE)	29.3 (25.0, 36.1)
Survival probability (95% CI) at		
Month 6	89.2% (80.8%, 94.0%)	85.2% (76.9%, 90.7%)
Month 12	77.8% (67.7%, 85.1%)	69.3% (59.4%, 77.2%)
Month 18	70.3% (59.5%, 78.8%)	46.8% (36.7%, 56.4%)
Month 24	57.0% (45.5%, 66.9%)	34.6% (25.2%, 44.2%)
Month 30	45.2% (33.8%, 56.0%)	22.9% (14.8%, 32.0%)
Month 36	32.7% (21.7%, 44.1%)	17.3% (10.1%, 26.1%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	0.61 (0.433, 0.870)	
p-value of 2-sided stratified log-rank test	0.0056	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	55	83
0	53 (96.4%)	80 (96.4%)
1	0	0
2	1 (1.8%)	0
3	0	1 (1.2%)
>=4	1 (1.8%)	2 (2.4%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with deterioration or death	37 (64.9%)	26 (55.3%)
Censored	20 (35.1%)	21 (44.7%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	5.3 (1.7, 7.5)	10.3 (3.8, 16.7)
50%	12.4 (6.8, 18.7)	18.5 (12.9, 24.6)
75%	26.3 (14.9, 34.0)	32.4 (20.0, NE)
Survival probability (95% CI) at		
Month 6	72.0% (55.9%, 83.0%)	87.8% (70.7%, 95.3%)
Month 12	52.2% (36.1%, 66.0%)	74.9% (56.0%, 86.6%)
Month 18	37.3% (22.8%, 51.7%)	55.4% (36.5%, 70.7%)
Month 24	32.3% (18.7%, 46.7%)	35.3% (19.1%, 51.9%)
Month 30	14.9% (6.1%, 27.5%)	31.8% (16.3%, 48.4%)
Month 36	8.9% (2.5%, 20.7%)	19.1% (6.9%, 35.8%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Deterioration - Death = Event
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Hazard ratio[b] (95% CI)	1.39 (0.820, 2.353)	
p-value of 2-sided stratified log-rank test	0.2006	
Number of subsequent visits with confirmation after first deterioration [n (%)]		
n	37	26
0	35 (94.6%)	25 (96.2%)
1	1 (2.7%)	0
2	0	1 (3.8%)
3	0	0
>=4	1 (2.7%)	0
p-value from Interaction Test[c]	0.0119	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	135	137
Status [n (%)]		
Number of subjects with improvement	8 (5.9%)	7 (5.1%)
Censored	127 (94.1%)	130 (94.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (22.8, NE)	NE (NE, NE)
50%	NE (NE, NE)	NE (NE, NE)
75%	NE (NE, NE)	NE (NE, NE)
Survival probability (95% CI) at		
Month 6	90.1% (79.2%, 95.4%)	88.0% (76.3%, 94.2%)
Month 12	88.1% (76.5%, 94.2%)	88.0% (76.3%, 94.2%)
Month 18	88.1% (76.5%, 94.2%)	88.0% (76.3%, 94.2%)
Month 24	83.9% (68.5%, 92.2%)	88.0% (76.3%, 94.2%)
Month 30	83.9% (68.5%, 92.2%)	88.0% (76.3%, 94.2%)
Month 36	83.9% (68.5%, 92.2%)	88.0% (76.3%, 94.2%)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Region: North America

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	1.11 (0.399, 3.115)	
p-value of 2-sided stratified log-rank test	0.8356	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	8	7
0	5 (62.5%)	5 (71.4%)
1	1 (12.5%)	2 (28.6%)
2	1 (12.5%)	0
3	0	0
>=4	1 (12.5%)	0

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Number of Subjects in the Subgroup	57	47
Status [n (%)]		
Number of subjects with improvement	0	1 (2.1%)
Censored	57 (100%)	46 (97.9%)
Estimates for time variable (months)		
Quartile (95% CI)[a]		
25%	NE (NE, NE)	NE (22.6, NE)
50%	NE (NE, NE)	NE (22.6, NE)
75%	NE (NE, NE)	NE (22.6, NE)
Survival probability (95% CI) at		
Month 6	100% (100%, 100%)	100% (100%, 100%)
Month 12	100% (100%, 100%)	100% (100%, 100%)
Month 18	100% (100%, 100%)	100% (100%, 100%)
Month 24	100% (100%, 100%)	80.0% (20.4%, 96.9%)
Month 30	100% (100%, 100%)	80.0% (20.4%, 96.9%)
Month 36	100% (100%, 100%)	NE (NE, NE)

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 2.2102 Kaplan Meier Analysis of EORTC QLQ-EN24 Dimension Scores Time to First Deterioration and Improvement by Region (ITT Analysis Set): MMRp/MSS Subjects

Scale/Item: EN24 Sexual Enjoyment Score 10-point Improvement
Region: Europe

Variable	Dostarlimab + Carboplatin/Paclitaxel (N=192)	Placebo + Carboplatin/Paclitaxel (N=184)
Inverse hazard ratio[b] (95% CI)	- (-, -)	
p-value of 2-sided stratified log-rank test	0.3173	
Number of subsequent visits with confirmation after first improvement [n (%)]		
n	0	1
0	0	0
1	0	0
2	0	0
3	0	0
>=4	0	1 (100%)
p-value from Interaction Test[c]	0.9942	

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: For QLQ-EN24 Functional Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline >= 10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline <= -10.
For QLQ-EN24 Symptom Scales, the scale score change from baseline are categorized as follows: Improvement: change from baseline <= -10; Stable: -10 < change from baseline < 10; Deterioration: change from baseline >= 10.
Program: t_2_2102_en24_ttiw_reg.sas, Output: t_2_2102_en24_ttiw_reg.rtf, Generated on: 02SEP2024 13:51, Data Cutoff Date: 22SEP2023

Table 3.8202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	96 (100%)	82 (100%)
	Censored	0	0
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.0 (NE, NE)	0.0 (0.0, 0.1)
	50%	0.1 (0.0, 0.1)	0.1 (0.1, 0.1)
	75%	0.2 (0.1, 0.3)	0.2 (0.1, 0.4)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8202_ttae_age.sas, Output: t_3_8202_ttae_age.rtf, Generated on: 06DEC2024 11:02,
Data Cutoff Date: 22SEP2023

Table 3.8202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 1	2.1% (0.4%, 6.6%)	3.7% (1.0%, 9.4%)
	Month 2	2.1% (0.4%, 6.6%)	1.2% (0.1%, 5.9%)
	Month 3	0 (NE, NE)	0 (NE, NE)
	Month 4	0 (NE, NE)	0 (NE, NE)
	Month 5	0 (NE, NE)	0 (NE, NE)
	Month 6	0 (NE, NE)	0 (NE, NE)
	Hazard ratio[b] (95% CI)	1.08 (0.787, 1.472)	
	p-value of 2-sided stratified log-rank test	0.5964	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8202_ttae_age.sas, Output: t_3_8202_ttae_age.rtf, Generated on: 06DEC2024 11:02,
Data Cutoff Date: 22SEP2023

Table 3.8202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	93 (100%)	99 (100%)
	Censored	0	0
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.0 (NE, NE)	0.0 (NE, NE)
	50%	0.1 (0.1, 0.1)	0.1 (0.1, 0.1)
	75%	0.2 (0.1, 0.3)	0.4 (0.2, 0.7)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8202_ttae_age.sas, Output: t_3_8202_ttae_age.rtf, Generated on: 06DEC2024 11:02,
Data Cutoff Date: 22SEP2023

Table 3.8202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 1	2.2% (0.4%, 6.8%)	8.1% (3.8%, 14.5%)
	Month 2	1.1% (0.1%, 5.2%)	3.0% (0.8%, 7.9%)
	Month 3	1.1% (0.1%, 5.2%)	1.0% (0.1%, 4.9%)
	Month 4	1.1% (0.1%, 5.2%)	0 (NE, NE)
	Month 5	1.1% (0.1%, 5.2%)	0 (NE, NE)
	Month 6	0 (NE, NE)	0 (NE, NE)
	Hazard ratio[b] (95% CI)	1.46 (1.071, 1.977)	
	p-value of 2-sided stratified log-rank test	0.0101	
	p-value from Interaction Test[c]	0.1355	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8202_ttae_age.sas, Output: t_3_8202_ttae_age.rtf, Generated on: 06DEC2024 11:02,
Data Cutoff Date: 22SEP2023

Table 3.8302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Region
(Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	133 (100%)	136 (100%)
	Censored	0	0
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.0 (NE, NE)	0.0 (NE, NE)
	50%	0.1 (0.0, 0.1)	0.1 (0.1, 0.1)
	75%	0.1 (0.1, 0.2)	0.3 (0.1, 0.5)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8302_ttae_reg.sas, Output: t_3_8302_ttae_reg.rtf, Generated on: 06DEC2024 11:01,
Data Cutoff Date: 22SEP2023

Table 3.8302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 1	1.5% (0.3%, 4.9%)	4.4% (1.8%, 8.8%)
	Month 2	0.8% (0.1%, 3.8%)	2.2% (0.6%, 5.8%)
	Month 3	0 (NE, NE)	0.7% (0.1%, 3.7%)
	Month 4	0 (NE, NE)	0 (NE, NE)
	Month 5	0 (NE, NE)	0 (NE, NE)
	Month 6	0 (NE, NE)	0 (NE, NE)
	Hazard ratio[b] (95% CI)	1.36 (1.053, 1.746)	
	p-value of 2-sided stratified log-rank test	0.0127	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8302_ttae_reg.sas, Output: t_3_8302_ttae_reg.rtf, Generated on: 06DEC2024 11:01,
Data Cutoff Date: 22SEP2023

Table 3.8302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Region
(Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	56 (100%)	45 (100%)
	Censored	0	0
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.1 (0.0, 0.1)	0.1 (0.0, 0.1)
	50%	0.1 (0.1, 0.2)	0.1 (0.1, 0.1)
	75%	0.3 (0.2, 0.5)	0.3 (0.1, 0.9)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8302_ttae_reg.sas, Output: t_3_8302_ttae_reg.rtf, Generated on: 06DEC2024 11:01,
Data Cutoff Date: 22SEP2023

Table 3.8302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 1	3.6% (0.7%, 10.9%)	11.1% (4.1%, 22.1%)
	Month 2	3.6% (0.7%, 10.9%)	2.2% (0.2%, 10.1%)
	Month 3	1.8% (0.1%, 8.3%)	0 (NE, NE)
	Month 4	1.8% (0.1%, 8.3%)	0 (NE, NE)
	Month 5	1.8% (0.1%, 8.3%)	0 (NE, NE)
	Month 6	0 (NE, NE)	0 (NE, NE)
	Hazard ratio[b] (95% CI)	1.10 (0.716, 1.694)	
	p-value of 2-sided stratified log-rank test	0.6017	
	p-value from Interaction Test[c]	0.3238	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8302_ttae_reg.sas, Output: t_3_8302_ttae_reg.rtf, Generated on: 06DEC2024 11:01,
Data Cutoff Date: 22SEP2023

Table 3.8402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	89 (100%)	87 (100%)
	Censored	0	0
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.0 (0.0, 0.1)	0.0 (NE, NE)
	50%	0.1 (0.1, 0.1)	0.1 (0.1, 0.1)
	75%	0.2 (0.1, 0.3)	0.3 (0.1, 0.6)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8402_ttae_dstat.sas, Output: t_3_8402_ttae_dstat.rtf, Generated on: 06DEC2024 11:01,
Data Cutoff Date: 22SEP2023

Table 3.8402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 1	4.5% (1.5%, 10.2%)	6.9% (2.8%, 13.5%)
	Month 2	3.4% (0.9%, 8.7%)	1.1% (0.1%, 5.6%)
	Month 3	1.1% (0.1%, 5.5%)	0 (NE, NE)
	Month 4	1.1% (0.1%, 5.5%)	0 (NE, NE)
	Month 5	1.1% (0.1%, 5.5%)	0 (NE, NE)
	Month 6	0 (NE, NE)	0 (NE, NE)
	Hazard ratio[b] (95% CI)	1.05 (0.773, 1.418)	
	p-value of 2-sided stratified log-rank test	0.7448	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8402_ttae_dstat.sas, Output: t_3_8402_ttae_dstat.rtf, Generated on: 06DEC2024 11:01,
Data Cutoff Date: 22SEP2023

Table 3.8402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	35 (100%)	30 (100%)
	Censored	0	0
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.0 (NE, NE)	0.0 (NE, NE)
	50%	0.1 (0.0, 0.1)	0.1 (0.0, 0.3)
	75%	0.2 (0.1, 0.4)	0.7 (0.1, 0.7)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8402_ttae_dstat.sas, Output: t_3_8402_ttae_dstat.rtf, Generated on: 06DEC2024 11:01,
Data Cutoff Date: 22SEP2023

Table 3.8402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 1	0 (NE, NE)	10.0% (2.5%, 23.6%)
	Month 2	0 (NE, NE)	6.7% (1.2%, 19.2%)
	Month 3	0 (NE, NE)	3.3% (0.2%, 14.5%)
	Month 4	0 (NE, NE)	0 (NE, NE)
	Month 5	0 (NE, NE)	0 (NE, NE)
	Month 6	0 (NE, NE)	0 (NE, NE)
	Hazard ratio[b] (95% CI)	1.92 (1.091, 3.370)	
	p-value of 2-sided stratified log-rank test	0.0151	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8402_ttae_dstat.sas, Output: t_3_8402_ttae_dstat.rtf, Generated on: 06DEC2024 11:01,
Data Cutoff Date: 22SEP2023

Table 3.8402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	65 (100%)	64 (100%)
	Censored	0	0
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.0 (NE, NE)	0.0 (0.0, 0.1)
	50%	0.1 (0.0, 0.1)	0.1 (0.1, 0.1)
	75%	0.1 (0.1, 0.2)	0.2 (0.1, 0.6)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8402_ttae_dstat.sas, Output: t_3_8402_ttae_dstat.rtf, Generated on: 06DEC2024 11:01,
Data Cutoff Date: 22SEP2023

Table 3.8402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 1	0 (NE, NE)	3.1% (0.6%, 9.7%)
	Month 2	0 (NE, NE)	1.6% (0.1%, 7.4%)
	Month 3	0 (NE, NE)	0 (NE, NE)
	Month 4	0 (NE, NE)	0 (NE, NE)
	Month 5	0 (NE, NE)	0 (NE, NE)
	Month 6	0 (NE, NE)	0 (NE, NE)
	Hazard ratio[b] (95% CI)	1.43 (0.989, 2.056)	
	p-value of 2-sided stratified log-rank test	0.0456	
	p-value from Interaction Test[c]	0.2035	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
NE = Not Estimable.
Program: t_3_8402_ttae_dstat.sas, Output: t_3_8402_ttae_dstat.rtf, Generated on: 06DEC2024 11:01,
Data Cutoff Date: 22SEP2023

Table 3.1402 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	38 (39.6%)	16 (19.5%)
	Censored	58 (60.4%)	66 (80.5%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	3.7 (1.2, 6.8)	17.3 (5.7, NE)
	50%	NE (8.6, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1402_ttsae_age.sas, Output: t_3_1402_ttsae_age.rtf, Generated on: 20SEP2024 10:00,

Data Cutoff Date: 22SEP2023

Table 3.1402 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	66.4% (55.7%, 75.1%)	82.9% (72.3%, 89.7%)
	Month 12	56.6% (44.7%, 66.8%)	81.2% (70.1%, 88.4%)
	Month 18	53.4% (40.7%, 64.6%)	74.9% (60.6%, 84.6%)
	Month 24	53.4% (40.7%, 64.6%)	74.9% (60.6%, 84.6%)
	Month 30	53.4% (40.7%, 64.6%)	74.9% (60.6%, 84.6%)
	Month 36	53.4% (40.7%, 64.6%)	74.9% (60.6%, 84.6%)
	Hazard ratio[b] (95% CI)	2.30 (1.279, 4.136)	
	p-value of 2-sided stratified log-rank test	0.0042	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_1402_ttsae_age.sas, Output: t_3_1402_ttsae_age.rtf, Generated on: 20SEP2024 10:00,
Data Cutoff Date: 22SEP2023

Table 3.1402 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	41 (44.1%)	32 (32.3%)
	Censored	52 (55.9%)	67 (67.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	2.8 (1.2, 6.8)	5.8 (2.8, 10.8)
	50%	23.5 (8.8, NE)	NE (10.9, NE)
	75%	NE (31.8, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_1402_ttsae_age.sas, Output: t_3_1402_ttsae_age.rtf, Generated on: 20SEP2024 10:00,
Data Cutoff Date: 22SEP2023

Table 3.1402 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	66.7% (55.9%, 75.4%)	74.9% (64.9%, 82.4%)
	Month 12	59.6% (48.2%, 69.2%)	61.6% (48.6%, 72.3%)
	Month 18	54.9% (42.7%, 65.6%)	58.0% (43.8%, 69.8%)
	Month 24	47.0% (32.3%, 60.4%)	58.0% (43.8%, 69.8%)
	Month 30	47.0% (32.3%, 60.4%)	58.0% (43.8%, 69.8%)
	Month 36	32.2% (14.3%, 51.8%)	58.0% (43.8%, 69.8%)
	Hazard ratio[b] (95% CI)	1.35 (0.840, 2.174)	
	p-value of 2-sided stratified log-rank test	0.2148	
	p-value from Interaction Test[c]	0.1402	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_1402_ttsae_age.sas, Output: t_3_1402_ttsae_age.rtf, Generated on: 20SEP2024 10:00,
Data Cutoff Date: 22SEP2023

Table 3.1502 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	51 (38.3%)	35 (25.7%)
	Censored	82 (61.7%)	101 (74.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	4.0 (2.3, 6.9)	8.7 (3.8, NE)
	50%	33.8 (19.1, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1502_ttsae_reg.sas, Output: t_3_1502_ttsae_reg.rtf, Generated on: 20SEP2024 10:00,

Data Cutoff Date: 22SEP2023

Table 3.1502 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	70.3% (61.5%, 77.4%)	78.8% (70.6%, 85.0%)
	Month 12	62.4% (53.0%, 70.4%)	69.5% (59.3%, 77.7%)
	Month 18	60.6% (50.8%, 69.1%)	66.7% (55.1%, 75.9%)
	Month 24	55.4% (43.8%, 65.5%)	66.7% (55.1%, 75.9%)
	Month 30	55.4% (43.8%, 65.5%)	66.7% (55.1%, 75.9%)
	Month 36	46.5% (31.4%, 60.3%)	66.7% (55.1%, 75.9%)
	Hazard ratio[b] (95% CI)	1.53 (0.985, 2.365)	
	p-value of 2-sided stratified log-rank test	0.0573	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_1502_ttsae_reg.sas, Output: t_3_1502_ttsae_reg.rtf, Generated on: 20SEP2024 10:00,
Data Cutoff Date: 22SEP2023

Table 3.1502 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	28 (50.0%)	13 (28.9%)
	Censored	28 (50.0%)	32 (71.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	1.3 (0.5, 4.6)	6.4 (2.8, NE)
	50%	10.3 (4.4, NE)	NE (12.6, NE)
	75%	NE (12.3, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1502_ttsae_reg.sas, Output: t_3_1502_ttsae_reg.rtf, Generated on: 20SEP2024 10:00,

Data Cutoff Date: 22SEP2023

Table 3.1502 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	57.9% (43.7%, 69.8%)	77.3% (61.9%, 87.1%)
	Month 12	47.3% (31.4%, 61.7%)	74.6% (58.8%, 85.1%)
	Month 18	35.5% (18.1%, 53.3%)	64.0% (43.7%, 78.6%)
	Month 24	35.5% (18.1%, 53.3%)	64.0% (43.7%, 78.6%)
	Month 30	35.5% (18.1%, 53.3%)	64.0% (43.7%, 78.6%)
	Month 36	35.5% (18.1%, 53.3%)	64.0% (43.7%, 78.6%)
	Hazard ratio[b] (95% CI)	2.16 (1.097, 4.237)	
	p-value of 2-sided stratified log-rank test	0.0230	
	p-value from Interaction Test[c]	0.2853	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_1502_ttsae_reg.sas, Output: t_3_1502_ttsae_reg.rtf, Generated on: 20SEP2024 10:00,
Data Cutoff Date: 22SEP2023

Table 3.1602 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	33 (37.1%)	26 (29.9%)
	Censored	56 (62.9%)	61 (70.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	3.8 (1.4, 8.9)	6.4 (2.2, 12.6)
	50%	33.8 (14.8, NE)	NE (12.6, NE)
	75%	NE (33.8, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1602_ttsae_dstat.sas, Output: t_3_1602_ttsae_dstat.rtf, Generated on: 20SEP2024 10:00,

Data Cutoff Date: 22SEP2023

Table 3.1602 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	69.9% (59.0%, 78.5%)	76.5% (65.9%, 84.2%)
	Month 12	64.7% (53.0%, 74.2%)	66.7% (53.8%, 76.8%)
	Month 18	61.4% (48.5%, 72.1%)	63.0% (48.6%, 74.5%)
	Month 24	57.8% (43.7%, 69.6%)	63.0% (48.6%, 74.5%)
	Month 30	57.8% (43.7%, 69.6%)	63.0% (48.6%, 74.5%)
	Month 36	41.1% (19.4%, 61.8%)	63.0% (48.6%, 74.5%)
	Hazard ratio[b] (95% CI)	1.25 (0.748, 2.104)	
	p-value of 2-sided stratified log-rank test	0.3910	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_1602_ttsae_dstat.sas, Output: t_3_1602_ttsae_dstat.rtf, Generated on: 20SEP2024 10:00,
Data Cutoff Date: 22SEP2023

Table 3.1602 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	16 (45.7%)	7 (23.3%)
	Censored	19 (54.3%)	23 (76.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	3.3 (0.8, 8.8)	5.8 (3.1, NE)
	50%	12.3 (3.8, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1602_ttsae_dstat.sas, Output: t_3_1602_ttsae_dstat.rtf, Generated on: 20SEP2024 10:00,

Data Cutoff Date: 22SEP2023

Table 3.1602 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	64.1% (45.4%, 77.9%)	74.8% (54.3%, 87.2%)
	Month 12	53.2% (34.4%, 68.9%)	74.8% (54.3%, 87.2%)
	Month 18	47.9% (28.6%, 64.9%)	74.8% (54.3%, 87.2%)
	Month 24	47.9% (28.6%, 64.9%)	74.8% (54.3%, 87.2%)
	Month 30	47.9% (28.6%, 64.9%)	74.8% (54.3%, 87.2%)
	Month 36	47.9% (28.6%, 64.9%)	74.8% (54.3%, 87.2%)
	Hazard ratio[b] (95% CI)	2.53 (0.991, 6.481)	
	p-value of 2-sided stratified log-rank test	0.0443	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_1602_ttsae_dstat.sas, Output: t_3_1602_ttsae_dstat.rtf, Generated on: 20SEP2024 10:00,
Data Cutoff Date: 22SEP2023

Table 3.1602 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	30 (46.2%)	15 (23.4%)
	Censored	35 (53.8%)	49 (76.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	3.7 (0.4, 5.9)	10.8 (5.7, NE)
	50%	16.8 (6.8, NE)	NE (17.3, NE)
	75%	NE (23.5, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1602_ttsae_dstat.sas, Output: t_3_1602_ttsae_dstat.rtf, Generated on: 20SEP2024 10:00,

Data Cutoff Date: 22SEP2023

Table 3.1602 Summary of Kaplan Meier Analysis of Time to Serious Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	63.5% (50.2%, 74.1%)	83.0% (70.6%, 90.5%)
	Month 12	53.4% (39.7%, 65.3%)	73.6% (57.7%, 84.4%)
	Month 18	49.3% (34.5%, 62.5%)	64.2% (44.8%, 78.3%)
	Month 24	41.1% (22.5%, 58.8%)	64.2% (44.8%, 78.3%)
	Month 30	41.1% (22.5%, 58.8%)	64.2% (44.8%, 78.3%)
	Month 36	41.1% (22.5%, 58.8%)	64.2% (44.8%, 78.3%)
	Hazard ratio[b] (95% CI)	2.22 (1.191, 4.124)	
	p-value of 2-sided stratified log-rank test	0.0100	
	p-value from Interaction Test[c]	0.2294	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_1602_ttsae_dstat.sas, Output: t_3_1602_ttsae_dstat.rtf, Generated on: 20SEP2024 10:00,
Data Cutoff Date: 22SEP2023

Table 3.2602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Death by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	2 (2.1%)	0
	Censored	94 (97.9%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_2602_ttaedth_age.sas, Output: t_3_2602_ttaedth_age.rtf, Generated on: 30AUG2024 16:09,
Data Cutoff Date: 22SEP2023

Table 3.2602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Death by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	1 (1.1%)	0
	Censored	92 (98.9%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_2602_ttaedth_age.sas, Output: t_3_2602_ttaedth_age.rtf, Generated on: 30AUG2024 16:09,
Data Cutoff Date: 22SEP2023

Table 3.2702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Death by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	0	0
	Censored	133 (100%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_2702_ttaedth_reg.sas, Output: t_3_2702_ttaedth_reg.rtf, Generated on: 30AUG2024 16:10,
Data Cutoff Date: 22SEP2023

Table 3.2702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Death by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	3 (5.4%)	0
	Censored	53 (94.6%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_2702_ttaedth_reg.sas, Output: t_3_2702_ttaedth_reg.rtf, Generated on: 30AUG2024 16:10,
Data Cutoff Date: 22SEP2023

Table 3.2802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Death by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_2802_ttaedth_dstat.sas, Output: t_3_2802_ttaedth_dstat.rtf, Generated on: 30AUG2024 16:10,
Data Cutoff Date: 22SEP2023

Table 3.2802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Death by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_2802_ttaedth_dstat.sas, Output: t_3_2802_ttaedth_dstat.rtf, Generated on: 30AUG2024 16:10,
Data Cutoff Date: 22SEP2023

Table 3.2802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Death by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	3 (4.6%)	0
	Censored	62 (95.4%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_2802_ttaedth_dstat.sas, Output: t_3_2802_ttaedth_dstat.rtf, Generated on: 30AUG2024 16:10,
Data Cutoff Date: 22SEP2023

Table 3.3002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	66 (68.8%)	47 (57.3%)
	Censored	30 (31.3%)	35 (42.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.7 (0.4, 1.4)	1.4 (0.7, 2.1)
	50%	3.5 (2.6, 7.3)	4.4 (2.7, 16.6)
	75%	17.5 (9.6, NE)	NE (16.6, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_3002_ttgr3_age.sas, Output: t_3_3002_ttgr3_age.rtf, Generated on: 12SEP2024 14:38,
Data Cutoff Date: 22SEP2023

Table 3.3002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	40.4% (30.4%, 50.2%)	47.8% (36.5%, 58.2%)
	Month 12	28.4% (18.6%, 39.0%)	41.9% (30.2%, 53.1%)
	Month 18	23.2% (13.4%, 34.5%)	35.8% (23.5%, 48.3%)
	Month 24	23.2% (13.4%, 34.5%)	35.8% (23.5%, 48.3%)
	Month 30	23.2% (13.4%, 34.5%)	35.8% (23.5%, 48.3%)
	Month 36	23.2% (13.4%, 34.5%)	35.8% (23.5%, 48.3%)
	Hazard ratio[b] (95% CI)	1.37 (0.939, 2.013)	
	p-value of 2-sided stratified log-rank test	0.0996	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_3002_ttgr3_age.sas, Output: t_3_3002_ttgr3_age.rtf, Generated on: 12SEP2024 14:38,
Data Cutoff Date: 22SEP2023

Table 3.3002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	69 (74.2%)	58 (58.6%)
	Censored	24 (25.8%)	41 (41.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.7 (0.3, 1.3)	1.4 (0.6, 2.0)
	50%	3.1 (2.0, 4.4)	4.1 (2.7, 8.7)
	75%	15.4 (6.8, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_3002_ttgr3_age.sas, Output: t_3_3002_ttgr3_age.rtf, Generated on: 12SEP2024 14:38,
Data Cutoff Date: 22SEP2023

Table 3.3002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	36.0% (26.3%, 45.7%)	44.1% (33.9%, 53.7%)
	Month 12	31.5% (22.3%, 41.1%)	37.2% (26.8%, 47.7%)
	Month 18	21.1% (11.7%, 32.5%)	37.2% (26.8%, 47.7%)
	Month 24	16.9% (7.5%, 29.5%)	37.2% (26.8%, 47.7%)
	Month 30	11.3% (3.0%, 25.8%)	37.2% (26.8%, 47.7%)
	Month 36	11.3% (3.0%, 25.8%)	NE (NE, NE)
	Hazard ratio[b] (95% CI)	1.37 (0.962, 1.955)	
	p-value of 2-sided stratified log-rank test	0.0804	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_3002_ttgr3_age.sas, Output: t_3_3002_ttgr3_age.rtf, Generated on: 12SEP2024 14:38,
Data Cutoff Date: 22SEP2023

Table 3.3002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	p-value from Interaction Test[c]	0.9496	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_3002_ttgr3_age.sas, Output: t_3_3002_ttgr3_age.rtf, Generated on: 12SEP2024 14:38,
Data Cutoff Date: 22SEP2023

Table 3.3102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Region
(Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	98 (73.7%)	74 (54.4%)
	Censored	35 (26.3%)	62 (45.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.7 (0.4, 1.4)	1.4 (1.0, 2.1)
	50%	3.4 (2.5, 4.1)	4.4 (3.5, 16.6)
	75%	16.7 (8.2, 36.7)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_3102_ttgr3_reg.sas, Output: t_3_3102_ttgr3_reg.rtf, Generated on: 12SEP2024 13:38,
Data Cutoff Date: 22SEP2023

Table 3.3102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	38.1% (29.7%, 46.3%)	47.7% (38.9%, 56.0%)
	Month 12	28.7% (20.9%, 37.0%)	42.7% (33.5%, 51.5%)
	Month 18	21.7% (13.8%, 30.8%)	40.2% (30.4%, 49.7%)
	Month 24	19.5% (11.7%, 28.9%)	40.2% (30.4%, 49.7%)
	Month 30	17.3% (9.7%, 26.9%)	40.2% (30.4%, 49.7%)
	Month 36	17.3% (9.7%, 26.9%)	40.2% (30.4%, 49.7%)
	Hazard ratio[b] (95% CI)	1.48 (1.093, 2.014)	
	p-value of 2-sided stratified log-rank test	0.0107	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_3102_ttgr3_reg.sas, Output: t_3_3102_ttgr3_reg.rtf, Generated on: 12SEP2024 13:38,
Data Cutoff Date: 22SEP2023

Table 3.3102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	37 (66.1%)	31 (68.9%)
	Censored	19 (33.9%)	14 (31.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.7 (0.3, 1.4)	0.7 (0.6, 1.6)
	50%	3.7 (1.4, 10.3)	3.4 (1.3, 7.7)
	75%	15.1 (10.3, NE)	NE (6.4, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_3102_ttgr3_reg.sas, Output: t_3_3102_ttgr3_reg.rtf, Generated on: 12SEP2024 13:38,
Data Cutoff Date: 22SEP2023

Table 3.3102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	38.4% (25.7%, 51.0%)	40.0% (25.8%, 53.8%)
	Month 12	34.9% (21.9%, 48.2%)	30.6% (17.1%, 45.3%)
	Month 18	24.5% (10.9%, 40.9%)	25.5% (12.1%, 41.3%)
	Month 24	24.5% (10.9%, 40.9%)	25.5% (12.1%, 41.3%)
	Month 30	24.5% (10.9%, 40.9%)	25.5% (12.1%, 41.3%)
	Month 36	24.5% (10.9%, 40.9%)	25.5% (12.1%, 41.3%)
	Hazard ratio[b] (95% CI)	1.08 (0.658, 1.760)	
	p-value of 2-sided stratified log-rank test	0.7611	
	p-value from Interaction Test[c]	0.1794	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_3102_ttgr3_reg.sas, Output: t_3_3102_ttgr3_reg.rtf, Generated on: 12SEP2024 13:38,
Data Cutoff Date: 22SEP2023

Table 3.3202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	60 (67.4%)	56 (64.4%)
	Censored	29 (32.6%)	31 (35.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.8 (0.5, 1.6)	1.0 (0.6, 1.4)
	50%	3.7 (2.1, 4.8)	3.5 (1.9, 4.5)
	75%	29.2 (11.1, NE)	NE (7.7, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_3202_ttgr3_dis.sas, Output: t_3_3202_ttgr3_dis.rtf, Generated on: 12SEP2024 13:44,
Data Cutoff Date: 22SEP2023

Table 3.3202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	38.7% (28.6%, 48.8%)	39.5% (29.1%, 49.6%)
	Month 12	33.1% (22.8%, 43.7%)	32.8% (22.7%, 43.4%)
	Month 18	26.7% (15.9%, 38.8%)	32.8% (22.7%, 43.4%)
	Month 24	26.7% (15.9%, 38.8%)	32.8% (22.7%, 43.4%)
	Month 30	22.9% (12.1%, 35.8%)	32.8% (22.7%, 43.4%)
	Month 36	22.9% (12.1%, 35.8%)	32.8% (22.7%, 43.4%)
	Hazard ratio[b] (95% CI)	0.98 (0.682, 1.417)	
	p-value of 2-sided stratified log-rank test	0.9311	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_3202_ttgr3_dis.sas, Output: t_3_3202_ttgr3_dis.rtf, Generated on: 12SEP2024 13:44,
Data Cutoff Date: 22SEP2023

Table 3.3202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	27 (77.1%)	15 (50.0%)
	Censored	8 (22.9%)	15 (50.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	1.0 (0.3, 2.1)	2.1 (0.5, 3.7)
	50%	3.4 (2.0, 8.2)	11.4 (2.8, NE)
	75%	12.3 (6.2, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_3202_ttgr3_dis.sas, Output: t_3_3202_ttgr3_dis.rtf, Generated on: 12SEP2024 13:44,
Data Cutoff Date: 22SEP2023

Table 3.3202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	41.6% (25.1%, 57.3%)	51.2% (31.8%, 67.6%)
	Month 12	25.6% (12.3%, 41.2%)	45.5% (25.8%, 63.3%)
	Month 18	20.5% (8.1%, 36.8%)	45.5% (25.8%, 63.3%)
	Month 24	20.5% (8.1%, 36.8%)	45.5% (25.8%, 63.3%)
	Month 30	20.5% (8.1%, 36.8%)	45.5% (25.8%, 63.3%)
	Month 36	20.5% (8.1%, 36.8%)	45.5% (25.8%, 63.3%)
	Hazard ratio[b] (95% CI)	2.15 (1.110, 4.182)	
	p-value of 2-sided stratified log-rank test	0.0197	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_3202_ttgr3_dis.sas, Output: t_3_3202_ttgr3_dis.rtf, Generated on: 12SEP2024 13:44,
Data Cutoff Date: 22SEP2023

Table 3.3202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	48 (73.8%)	34 (53.1%)
	Censored	17 (26.2%)	30 (46.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.4 (0.2, 1.3)	1.6 (0.7, 2.7)
	50%	2.8 (1.4, 4.6)	8.7 (2.8, NE)
	75%	16.7 (5.6, NE)	NE (16.6, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_3202_ttgr3_dis.sas, Output: t_3_3202_ttgr3_dis.rtf, Generated on: 12SEP2024 13:44,
Data Cutoff Date: 22SEP2023

Table 3.3202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	35.7% (24.2%, 47.4%)	51.9% (38.9%, 63.5%)
	Month 12	29.8% (18.8%, 41.7%)	46.3% (32.6%, 58.9%)
	Month 18	18.9% (8.5%, 32.5%)	38.8% (24.4%, 53.0%)
	Month 24	14.2% (4.8%, 28.6%)	38.8% (24.4%, 53.0%)
	Month 30	14.2% (4.8%, 28.6%)	38.8% (24.4%, 53.0%)
	Month 36	14.2% (4.8%, 28.6%)	38.8% (24.4%, 53.0%)
	Hazard ratio[b] (95% CI)	1.74 (1.119, 2.699)	
	p-value of 2-sided stratified log-rank test	0.0131	
	p-value from Interaction Test[c]	0.0545	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_3202_ttgr3_dis.sas, Output: t_3_3202_ttgr3_dis.rtf, Generated on: 12SEP2024 13:44,
Data Cutoff Date: 22SEP2023

Table 3.4202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Age Group
(Safety Analysis MMRp/MSS): All Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	20 (20.8%)	12 (14.6%)
	Censored	76 (79.2%)	70 (85.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	16.6 (9.7, NE)	37.8 (12.1, NE)
	50%	NE (34.7, NE)	NE (37.8, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4202_ttae_disc_age.sas, Output: t_3_4202_ttae_disc_age.rtf, Generated on: 23SEP2024 08:03,
Data Cutoff Date: 22SEP2023

Table 3.4202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Age Group
(Safety Analysis MMRp/MSS): All Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	84.9% (75.8%, 90.8%)	88.6% (79.2%, 93.9%)
	Month 12	79.1% (67.9%, 86.8%)	86.8% (76.8%, 92.7%)
	Month 18	73.4% (59.7%, 83.0%)	84.1% (72.4%, 91.2%)
	Month 24	73.4% (59.7%, 83.0%)	84.1% (72.4%, 91.2%)
	Month 30	73.4% (59.7%, 83.0%)	84.1% (72.4%, 91.2%)
	Month 36	66.0% (46.0%, 80.1%)	84.1% (72.4%, 91.2%)
	Hazard ratio[b] (95% CI)	1.32 (0.646, 2.711)	
	p-value of 2-sided stratified log-rank test	0.4424	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4202_ttae_disc_age.sas, Output: t_3_4202_ttae_disc_age.rtf, Generated on: 23SEP2024 08:03,
Data Cutoff Date: 22SEP2023

Table 3.4202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Age Group
(Safety Analysis MMRp/MSS): All Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	30 (32.3%)	17 (17.2%)
	Censored	63 (67.7%)	82 (82.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	6.9 (2.8, 19.5)	NE (5.6, NE)
	50%	36.5 (19.5, NE)	NE (NE, NE)
	75%	NE (36.5, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4202_ttae_disc_age.sas, Output: t_3_4202_ttae_disc_age.rtf, Generated on: 23SEP2024 08:03,
Data Cutoff Date: 22SEP2023

Table 3.4202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Age Group
(Safety Analysis MMRp/MSS): All Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	75.4% (65.1%, 83.1%)	82.0% (72.6%, 88.4%)
	Month 12	74.1% (63.5%, 82.0%)	82.0% (72.6%, 88.4%)
	Month 18	65.9% (52.5%, 76.3%)	82.0% (72.6%, 88.4%)
	Month 24	58.7% (43.1%, 71.3%)	82.0% (72.6%, 88.4%)
	Month 30	58.7% (43.1%, 71.3%)	82.0% (72.6%, 88.4%)
	Month 36	51.4% (32.0%, 67.7%)	82.0% (72.6%, 88.4%)
	Hazard ratio[b] (95% CI)	1.88 (1.015, 3.486)	
	p-value of 2-sided stratified log-rank test	0.0407	
	p-value from Interaction Test[c]	0.5705	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4202_ttae_disc_age.sas, Output: t_3_4202_ttae_disc_age.rtf, Generated on: 23SEP2024 08:03,
Data Cutoff Date: 22SEP2023

Table 3.4302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	32 (24.1%)	19 (14.0%)
	Censored	101 (75.9%)	117 (86.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	15.4 (9.7, 34.7)	37.8 (37.8, NE)
	50%	NE (34.7, NE)	NE (37.8, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4302_ttae_disc_reg.sas, Output: t_3_4302_ttae_disc_reg.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.4302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	84.4% (76.8%, 89.6%)	86.7% (79.4%, 91.5%)
	Month 12	79.6% (70.8%, 86.0%)	86.7% (79.4%, 91.5%)
	Month 18	69.9% (58.2%, 78.9%)	84.4% (75.5%, 90.3%)
	Month 24	67.1% (54.4%, 77.0%)	84.4% (75.5%, 90.3%)
	Month 30	67.1% (54.4%, 77.0%)	84.4% (75.5%, 90.3%)
	Month 36	62.6% (47.6%, 74.5%)	84.4% (75.5%, 90.3%)
	Hazard ratio[b] (95% CI)	1.56 (0.873, 2.787)	
	p-value of 2-sided stratified log-rank test	0.1295	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4302_ttae_disc_reg.sas, Output: t_3_4302_ttae_disc_reg.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.4302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	18 (32.1%)	10 (22.2%)
	Censored	38 (67.9%)	35 (77.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	3.7 (1.4, 34.7)	NE (2.2, NE)
	50%	34.7 (19.5, NE)	NE (NE, NE)
	75%	NE (34.7, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4302_ttae_disc_reg.sas, Output: t_3_4302_ttae_disc_reg.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.4302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	70.7% (56.6%, 80.9%)	79.7% (64.6%, 88.9%)
	Month 12	70.7% (56.6%, 80.9%)	76.6% (60.7%, 86.8%)
	Month 18	70.7% (56.6%, 80.9%)	76.6% (60.7%, 86.8%)
	Month 24	63.6% (44.1%, 77.9%)	76.6% (60.7%, 86.8%)
	Month 30	63.6% (44.1%, 77.9%)	76.6% (60.7%, 86.8%)
	Month 36	42.4% (10.1%, 72.6%)	76.6% (60.7%, 86.8%)
	Hazard ratio[b] (95% CI)	1.64 (0.750, 3.592)	
	p-value of 2-sided stratified log-rank test	0.2097	
	p-value from Interaction Test[c]	0.8529	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4302_ttae_disc_reg.sas, Output: t_3_4302_ttae_disc_reg.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.4402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	20 (22.5%)	19 (21.8%)
	Censored	69 (77.5%)	68 (78.2%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	16.6 (3.3, NE)	12.1 (2.9, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4402_ttae_disc_dstat.sas, Output: t_3_4402_ttae_disc_dstat.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.4402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	81.8% (71.9%, 88.4%)	79.7% (69.4%, 86.9%)
	Month 12	79.3% (68.4%, 86.9%)	78.0% (67.2%, 85.6%)
	Month 18	72.7% (58.4%, 82.8%)	73.9% (60.1%, 83.5%)
	Month 24	68.2% (51.6%, 80.1%)	73.9% (60.1%, 83.5%)
	Month 30	68.2% (51.6%, 80.1%)	73.9% (60.1%, 83.5%)
	Month 36	68.2% (51.6%, 80.1%)	73.9% (60.1%, 83.5%)
	Hazard ratio[b] (95% CI)	0.95 (0.503, 1.778)	
	p-value of 2-sided stratified log-rank test	0.8613	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4402_ttae_disc_dstat.sas, Output: t_3_4402_ttae_disc_dstat.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.4402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	11 (31.4%)	5 (16.7%)
	Censored	24 (68.6%)	25 (83.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	9.7 (2.1, 34.7)	NE (2.8, NE)
	50%	34.7 (19.5, NE)	NE (NE, NE)
	75%	NE (34.7, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4402_ttae_disc_dstat.sas, Output: t_3_4402_ttae_disc_dstat.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.4402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	79.8% (62.2%, 89.8%)	82.7% (63.2%, 92.5%)
	Month 12	72.8% (54.0%, 84.9%)	82.7% (63.2%, 92.5%)
	Month 18	72.8% (54.0%, 84.9%)	82.7% (63.2%, 92.5%)
	Month 24	62.4% (35.7%, 80.6%)	82.7% (63.2%, 92.5%)
	Month 30	62.4% (35.7%, 80.6%)	82.7% (63.2%, 92.5%)
	Month 36	46.8% (15.8%, 73.2%)	82.7% (63.2%, 92.5%)
	Hazard ratio[b] (95% CI)	2.41 (0.762, 7.599)	
	p-value of 2-sided stratified log-rank test	0.1207	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4402_ttae_disc_dstat.sas, Output: t_3_4402_ttae_disc_dstat.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.4402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	19 (29.2%)	5 (7.8%)
	Censored	46 (70.8%)	59 (92.2%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	14.1 (3.5, 34.7)	37.8 (37.8, NE)
	50%	36.5 (16.7, NE)	37.8 (37.8, NE)
	75%	NE (36.5, NE)	NE (37.8, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4402_ttae_disc_dstat.sas, Output: t_3_4402_ttae_disc_dstat.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.4402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events Leading to Study Drug Discontinuation by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	78.5% (65.8%, 87.0%)	93.3% (83.1%, 97.5%)
	Month 12	75.8% (62.2%, 85.1%)	93.3% (83.1%, 97.5%)
	Month 18	64.9% (47.9%, 77.6%)	93.3% (83.1%, 97.5%)
	Month 24	64.9% (47.9%, 77.6%)	93.3% (83.1%, 97.5%)
	Month 30	64.9% (47.9%, 77.6%)	93.3% (83.1%, 97.5%)
	Month 36	56.8% (35.1%, 73.7%)	93.3% (83.1%, 97.5%)
	Hazard ratio[b] (95% CI)	3.51 (1.304, 9.451)	
	p-value of 2-sided stratified log-rank test	0.0081	
	p-value from Interaction Test[c]	0.0788	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_4402_ttae_disc_dstat.sas, Output: t_3_4402_ttae_disc_dstat.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	52 (54.2%)	29 (35.4%)
	Censored	44 (45.8%)	53 (64.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.7 (0.3, 2.2)	0.8 (0.7, 11.1)
	50%	7.6 (3.4, 15.7)	NE (11.3, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	50.0% (39.5%, 59.7%)	70.2% (58.9%, 79.0%)
	Month 12	41.4% (29.9%, 52.5%)	61.5% (48.4%, 72.2%)
	Month 18	37.6% (25.3%, 50.0%)	61.5% (48.4%, 72.2%)
	Month 24	37.6% (25.3%, 50.0%)	61.5% (48.4%, 72.2%)
	Month 30	37.6% (25.3%, 50.0%)	56.8% (41.5%, 69.5%)
	Month 36	37.6% (25.3%, 50.0%)	56.8% (41.5%, 69.5%)
	Hazard ratio[b] (95% CI)	1.74 (1.098, 2.746)	
	p-value of 2-sided stratified log-rank test	0.0154	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	50 (53.8%)	36 (36.4%)
	Censored	43 (46.2%)	63 (63.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.7 (0.4, 2.2)	1.4 (0.5, 5.9)
	50%	9.5 (3.7, 33.6)	NE (11.1, NE)
	75%	34.5 (22.6, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	57.0% (46.1%, 66.5%)	65.6% (55.0%, 74.2%)
	Month 12	49.5% (38.3%, 59.7%)	58.8% (46.4%, 69.3%)
	Month 18	41.6% (29.2%, 53.5%)	58.8% (46.4%, 69.3%)
	Month 24	37.4% (24.1%, 50.7%)	58.8% (46.4%, 69.3%)
	Month 30	37.4% (24.1%, 50.7%)	58.8% (46.4%, 69.3%)
	Month 36	23.4% (8.6%, 42.3%)	58.8% (46.4%, 69.3%)
	Hazard ratio[b] (95% CI)	1.39 (0.890, 2.156)	
	p-value of 2-sided stratified log-rank test	0.1474	
	p-value from Interaction Test[c]	0.5511	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	41 (42.7%)	13 (15.9%)
	Censored	55 (57.3%)	69 (84.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	3.0 (0.9, 4.1)	NE (8.7, NE)
	50%	NE (4.8, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	59.4% (48.4%, 68.8%)	91.3% (82.5%, 95.7%)
	Month 12	50.4% (38.0%, 61.6%)	80.5% (67.3%, 88.8%)
	Month 18	50.4% (38.0%, 61.6%)	80.5% (67.3%, 88.8%)
	Month 24	50.4% (38.0%, 61.6%)	80.5% (67.3%, 88.8%)
	Month 30	50.4% (38.0%, 61.6%)	76.0% (59.8%, 86.4%)
	Month 36	50.4% (38.0%, 61.6%)	76.0% (59.8%, 86.4%)
	Hazard ratio[b] (95% CI)	3.36 (1.793, 6.300)	
	p-value of 2-sided stratified log-rank test	<.0001	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	45 (48.4%)	26 (26.3%)
	Censored	48 (51.6%)	73 (73.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	2.0 (0.4, 4.2)	6.9 (1.3, NE)
	50%	13.8 (6.9, 34.5)	NE (NE, NE)
	75%	NE (33.6, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	63.5% (52.6%, 72.5%)	75.8% (65.7%, 83.2%)
	Month 12	54.2% (42.7%, 64.4%)	69.4% (57.2%, 78.8%)
	Month 18	43.9% (30.8%, 56.3%)	69.4% (57.2%, 78.8%)
	Month 24	43.9% (30.8%, 56.3%)	69.4% (57.2%, 78.8%)
	Month 30	43.9% (30.8%, 56.3%)	69.4% (57.2%, 78.8%)
	Month 36	27.4% (10.3%, 48.0%)	69.4% (57.2%, 78.8%)
	Hazard ratio[b] (95% CI)	1.82 (1.107, 3.003)	
	p-value of 2-sided stratified log-rank test	0.0170	
	p-value from Interaction Test[c]	0.1487	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	20 (20.8%)	18 (22.0%)
	Censored	76 (79.2%)	64 (78.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (0.8, NE)	NE (0.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	80.1% (70.6%, 86.8%)	77.7% (67.0%, 85.3%)
	Month 12	80.1% (70.6%, 86.8%)	77.7% (67.0%, 85.3%)
	Month 18	75.9% (62.6%, 85.0%)	77.7% (67.0%, 85.3%)
	Month 24	75.9% (62.6%, 85.0%)	77.7% (67.0%, 85.3%)
	Month 30	75.9% (62.6%, 85.0%)	77.7% (67.0%, 85.3%)
	Month 36	75.9% (62.6%, 85.0%)	77.7% (67.0%, 85.3%)
	Hazard ratio[b] (95% CI)	0.94 (0.498, 1.786)	
	p-value of 2-sided stratified log-rank test	0.8604	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	13 (14.0%)	14 (14.1%)
	Censored	80 (86.0%)	85 (85.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (22.6, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	86.8% (78.0%, 92.3%)	85.8% (77.2%, 91.3%)
	Month 12	86.8% (78.0%, 92.3%)	85.8% (77.2%, 91.3%)
	Month 18	86.8% (78.0%, 92.3%)	85.8% (77.2%, 91.3%)
	Month 24	81.4% (65.3%, 90.5%)	85.8% (77.2%, 91.3%)
	Month 30	81.4% (65.3%, 90.5%)	85.8% (77.2%, 91.3%)
	Month 36	81.4% (65.3%, 90.5%)	85.8% (77.2%, 91.3%)
	Hazard ratio[b] (95% CI)	0.95 (0.447, 2.033)	
	p-value of 2-sided stratified log-rank test	0.9099	
	p-value from Interaction Test[c]	0.9471	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	10 (10.4%)	9 (11.0%)
	Censored	86 (89.6%)	73 (89.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (17.9, NE)	NE (27.1, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	93.6% (86.2%, 97.1%)	93.7% (85.6%, 97.3%)
	Month 12	93.6% (86.2%, 97.1%)	87.4% (75.5%, 93.7%)
	Month 18	86.5% (71.5%, 94.0%)	87.4% (75.5%, 93.7%)
	Month 24	82.2% (64.5%, 91.6%)	87.4% (75.5%, 93.7%)
	Month 30	76.3% (55.0%, 88.5%)	82.8% (66.6%, 91.6%)
	Month 36	76.3% (55.0%, 88.5%)	82.8% (66.6%, 91.6%)
	Hazard ratio[b] (95% CI)	0.87 (0.353, 2.150)	
	p-value of 2-sided stratified log-rank test	0.7625	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	17 (18.3%)	14 (14.1%)
	Censored	76 (81.7%)	85 (85.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	13.8 (11.1, NE)	NE (11.1, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	88.8% (80.2%, 93.8%)	87.6% (79.2%, 92.8%)
	Month 12	83.1% (72.0%, 90.1%)	82.4% (70.3%, 89.9%)
	Month 18	74.7% (60.1%, 84.5%)	82.4% (70.3%, 89.9%)
	Month 24	70.3% (53.6%, 81.9%)	82.4% (70.3%, 89.9%)
	Month 30	70.3% (53.6%, 81.9%)	82.4% (70.3%, 89.9%)
	Month 36	70.3% (53.6%, 81.9%)	82.4% (70.3%, 89.9%)
	Hazard ratio[b] (95% CI)	1.13 (0.552, 2.307)	
	p-value of 2-sided stratified log-rank test	0.7369	
	p-value from Interaction Test[c]	0.6946	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	16 (16.7%)	4 (4.9%)
	Censored	80 (83.3%)	78 (95.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (10.3, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	84.3% (75.4%, 90.3%)	94.9% (87.1%, 98.1%)
	Month 12	81.9% (71.6%, 88.8%)	94.9% (87.1%, 98.1%)
	Month 18	81.9% (71.6%, 88.8%)	94.9% (87.1%, 98.1%)
	Month 24	81.9% (71.6%, 88.8%)	94.9% (87.1%, 98.1%)
	Month 30	81.9% (71.6%, 88.8%)	94.9% (87.1%, 98.1%)
	Month 36	81.9% (71.6%, 88.8%)	94.9% (87.1%, 98.1%)
	Hazard ratio[b] (95% CI)	3.62 (1.208, 10.821)	
	p-value of 2-sided stratified log-rank test	0.0141	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	20 (21.5%)	6 (6.1%)
	Censored	73 (78.5%)	93 (93.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	33.6 (0.7, NE)	NE (NE, NE)
	50%	NE (33.6, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	80.4% (70.7%, 87.2%)	93.8% (86.7%, 97.2%)
	Month 12	80.4% (70.7%, 87.2%)	93.8% (86.7%, 97.2%)
	Month 18	80.4% (70.7%, 87.2%)	93.8% (86.7%, 97.2%)
	Month 24	80.4% (70.7%, 87.2%)	93.8% (86.7%, 97.2%)
	Month 30	80.4% (70.7%, 87.2%)	93.8% (86.7%, 97.2%)
	Month 36	58.6% (28.6%, 79.6%)	93.8% (86.7%, 97.2%)
	Hazard ratio[b] (95% CI)	3.49 (1.378, 8.819)	
	p-value of 2-sided stratified log-rank test	0.0052	
	p-value from Interaction Test[c]	0.9845	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Endocrinopathies

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	16 (16.7%)	1 (1.2%)
	Censored	80 (83.3%)	81 (98.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (7.6, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Endocrinopathies

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	86.3% (77.1%, 92.0%)	100% (100%, 100%)
	Month 12	77.2% (64.2%, 86.0%)	97.3% (82.3%, 99.6%)
	Month 18	77.2% (64.2%, 86.0%)	97.3% (82.3%, 99.6%)
	Month 24	77.2% (64.2%, 86.0%)	97.3% (82.3%, 99.6%)
	Month 30	77.2% (64.2%, 86.0%)	97.3% (82.3%, 99.6%)
	Month 36	77.2% (64.2%, 86.0%)	97.3% (82.3%, 99.6%)
	Hazard ratio[b] (95% CI)	15.13 (2.004, 114.238)	
	p-value of 2-sided stratified log-rank test	0.0004	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Endocrinopathies

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	12 (12.9%)	6 (6.1%)
	Censored	81 (87.1%)	93 (93.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (13.8, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Endocrinopathies

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	89.9% (80.7%, 94.8%)	94.6% (87.5%, 97.7%)
	Month 12	86.5% (76.2%, 92.6%)	93.1% (85.1%, 96.9%)
	Month 18	83.4% (70.9%, 90.9%)	93.1% (85.1%, 96.9%)
	Month 24	77.5% (58.9%, 88.4%)	93.1% (85.1%, 96.9%)
	Month 30	77.5% (58.9%, 88.4%)	93.1% (85.1%, 96.9%)
	Month 36	77.5% (58.9%, 88.4%)	93.1% (85.1%, 96.9%)
	Hazard ratio[b] (95% CI)	2.08 (0.777, 5.574)	
	p-value of 2-sided stratified log-rank test	0.1362	
	p-value from Interaction Test[c]	0.0765	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Hepatic

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	8 (8.3%)	2 (2.4%)
	Censored	88 (91.7%)	80 (97.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Hepatic

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	92.0% (83.9%, 96.1%)	97.5% (90.4%, 99.4%)
	Month 12	90.0% (80.6%, 95.0%)	97.5% (90.4%, 99.4%)
	Month 18	90.0% (80.6%, 95.0%)	97.5% (90.4%, 99.4%)
	Month 24	90.0% (80.6%, 95.0%)	97.5% (90.4%, 99.4%)
	Month 30	90.0% (80.6%, 95.0%)	97.5% (90.4%, 99.4%)
	Month 36	90.0% (80.6%, 95.0%)	97.5% (90.4%, 99.4%)
	Hazard ratio[b] (95% CI)	3.29 (0.697, 15.496)	
	p-value of 2-sided stratified log-rank test	0.1109	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Hepatic

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	5 (5.4%)	3 (3.0%)
	Censored	88 (94.6%)	96 (97.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Hepatic

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	96.7% (90.2%, 98.9%)	96.5% (89.4%, 98.9%)
	Month 12	95.3% (87.8%, 98.2%)	96.5% (89.4%, 98.9%)
	Month 18	91.7% (78.7%, 96.9%)	96.5% (89.4%, 98.9%)
	Month 24	91.7% (78.7%, 96.9%)	96.5% (89.4%, 98.9%)
	Month 30	91.7% (78.7%, 96.9%)	96.5% (89.4%, 98.9%)
	Month 36	91.7% (78.7%, 96.9%)	96.5% (89.4%, 98.9%)
	Hazard ratio[b] (95% CI)	2.70 (0.520, 14.004)	
	p-value of 2-sided stratified log-rank test	0.2189	
	p-value from Interaction Test[c]	0.5387	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Gastrointestinal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	1 (1.0%)	1 (1.2%)
	Censored	95 (99.0%)	81 (98.8%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Gastrointestinal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	2 (2.2%)	1 (1.0%)
	Censored	91 (97.8%)	98 (99.0%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pulmonary

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	3 (3.1%)	0
	Censored	93 (96.9%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pulmonary

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	2 (2.2%)	0
	Censored	91 (97.8%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
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Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Cardiovascular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	2 (2.1%)	0
	Censored	94 (97.9%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Cardiovascular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Ocular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Ocular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	2 (2.2%)	0
	Censored	91 (97.8%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Nervous System

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	1 (1.0%)	0
	Censored	95 (99.0%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Nervous System

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pancreatitis

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pancreatitis

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	1 (1.1%)	0
	Censored	92 (98.9%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_4602_ttirae_age.sas, Output: t_3_4602_ttirae_age.rtf, Generated on: 10SEP2024 16:51,
Data Cutoff Date: 22SEP2023

Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	76 (57.1%)	51 (37.5%)
	Censored	57 (42.9%)	85 (62.5%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.7 (0.4, 0.9)	0.8 (0.7, 5.6)
	50%	4.8 (3.0, 15.7)	NE (11.1, NE)
	75%	NE (33.6, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_4702_ttirae_reg.sas, Output: t_3_4702_ttirae_reg.rtf, Generated on: 12SEP2024 11:02,
Data Cutoff Date: 22SEP2023

Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	49.4% (40.5%, 57.7%)	64.8% (55.9%, 72.4%)
	Month 12	42.8% (33.7%, 51.5%)	57.0% (46.5%, 66.3%)
	Month 18	38.9% (29.4%, 48.4%)	57.0% (46.5%, 66.3%)
	Month 24	38.9% (29.4%, 48.4%)	57.0% (46.5%, 66.3%)
	Month 30	38.9% (29.4%, 48.4%)	57.0% (46.5%, 66.3%)
	Month 36	27.3% (13.4%, 43.2%)	57.0% (46.5%, 66.3%)
	Hazard ratio[b] (95% CI)	1.57 (1.092, 2.249)	
	p-value of 2-sided stratified log-rank test	0.0133	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_4702_ttirae_reg.sas, Output: t_3_4702_ttirae_reg.rtf, Generated on: 12SEP2024 11:02,
Data Cutoff Date: 22SEP2023

Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	26 (46.4%)	14 (31.1%)
	Censored	30 (53.6%)	31 (68.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	2.6 (0.4, 4.8)	7.7 (0.5, NE)
	50%	12.1 (4.8, NE)	NE (11.1, NE)
	75%	NE (17.9, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_4702_ttirae_reg.sas, Output: t_3_4702_ttirae_reg.rtf, Generated on: 12SEP2024 11:02,
Data Cutoff Date: 22SEP2023

Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	62.9% (48.4%, 74.3%)	75.3% (59.9%, 85.5%)
	Month 12	52.4% (36.0%, 66.5%)	67.6% (49.6%, 80.3%)
	Month 18	38.8% (19.5%, 57.9%)	67.6% (49.6%, 80.3%)
	Month 24	29.1% (10.0%, 51.6%)	67.6% (49.6%, 80.3%)
	Month 30	29.1% (10.0%, 51.6%)	57.9% (33.5%, 76.1%)
	Month 36	NE (NE, NE)	57.9% (33.5%, 76.1%)
	Hazard ratio[b] (95% CI)	1.69 (0.856, 3.328)	
	p-value of 2-sided stratified log-rank test	0.1263	
	p-value from Interaction Test[c]	0.9009	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_4702_ttirae_reg.sas, Output: t_3_4702_ttirae_reg.rtf, Generated on: 12SEP2024 11:02,
Data Cutoff Date: 22SEP2023

Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	64 (48.1%)	29 (21.3%)
	Censored	69 (51.9%)	107 (78.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	2.0 (0.7, 3.7)	11.3 (5.9, NE)
	50%	12.5 (5.6, NE)	NE (NE, NE)
	75%	NE (34.5, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_4702_ttirae_reg.sas, Output: t_3_4702_ttirae_reg.rtf, Generated on: 12SEP2024 11:02,
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	58.7% (49.6%, 66.7%)	82.0% (74.1%, 87.7%)
	Month 12	50.4% (40.8%, 59.3%)	73.4% (63.1%, 81.3%)
	Month 18	46.9% (36.8%, 56.4%)	73.4% (63.1%, 81.3%)
	Month 24	46.9% (36.8%, 56.4%)	73.4% (63.1%, 81.3%)
	Month 30	46.9% (36.8%, 56.4%)	73.4% (63.1%, 81.3%)
	Month 36	34.7% (19.1%, 51.0%)	73.4% (63.1%, 81.3%)
	Hazard ratio[b] (95% CI)	2.53 (1.618, 3.959)	
	p-value of 2-sided stratified log-rank test	<.0001	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_4702_ttirae_reg.sas, Output: t_3_4702_ttirae_reg.rtf, Generated on: 12SEP2024 11:02,
Data Cutoff Date: 22SEP2023

Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	22 (39.3%)	10 (22.2%)
	Censored	34 (60.7%)	35 (77.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	3.3 (0.4, 7.6)	27.1 (3.5, NE)
	50%	17.9 (7.6, NE)	NE (27.1, NE)
	75%	NE (17.9, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Data Cutoff Date: 22SEP2023

Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	68.2% (53.7%, 78.9%)	84.0% (69.3%, 92.1%)
	Month 12	57.5% (40.5%, 71.2%)	76.2% (58.0%, 87.3%)
	Month 18	44.3% (24.1%, 62.8%)	76.2% (58.0%, 87.3%)
	Month 24	44.3% (24.1%, 62.8%)	76.2% (58.0%, 87.3%)
	Month 30	44.3% (24.1%, 62.8%)	66.6% (40.7%, 83.3%)
	Month 36	44.3% (24.1%, 62.8%)	66.6% (40.7%, 83.3%)
	Hazard ratio[b] (95% CI)	1.89 (0.880, 4.079)	
	p-value of 2-sided stratified log-rank test	0.0970	
	p-value from Interaction Test[c]	0.7002	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	26 (19.5%)	26 (19.1%)
	Censored	107 (80.5%)	110 (80.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (2.1, NE)	NE (1.4, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	81.1% (73.3%, 86.8%)	80.6% (72.8%, 86.4%)
	Month 12	81.1% (73.3%, 86.8%)	80.6% (72.8%, 86.4%)
	Month 18	78.7% (69.4%, 85.4%)	80.6% (72.8%, 86.4%)
	Month 24	78.7% (69.4%, 85.4%)	80.6% (72.8%, 86.4%)
	Month 30	78.7% (69.4%, 85.4%)	80.6% (72.8%, 86.4%)
	Month 36	78.7% (69.4%, 85.4%)	80.6% (72.8%, 86.4%)
	Hazard ratio[b] (95% CI)	1.01 (0.585, 1.740)	
	p-value of 2-sided stratified log-rank test	0.9739	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	7 (12.5%)	6 (13.3%)
	Censored	49 (87.5%)	39 (86.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (22.6, NE)	NE (2.1, NE)
	50%	NE (22.6, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	89.0% (77.0%, 94.9%)	86.7% (72.7%, 93.8%)
	Month 12	89.0% (77.0%, 94.9%)	86.7% (72.7%, 93.8%)
	Month 18	89.0% (77.0%, 94.9%)	86.7% (72.7%, 93.8%)
	Month 24	77.8% (46.7%, 92.1%)	86.7% (72.7%, 93.8%)
	Month 30	77.8% (46.7%, 92.1%)	86.7% (72.7%, 93.8%)
	Month 36	77.8% (46.7%, 92.1%)	86.7% (72.7%, 93.8%)
	Hazard ratio[b] (95% CI)	0.91 (0.300, 2.743)	
	p-value of 2-sided stratified log-rank test	0.8700	
	p-value from Interaction Test[c]	0.9238	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	21 (15.8%)	18 (13.2%)
	Censored	112 (84.2%)	118 (86.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	29.3 (12.5, NE)	NE (11.3, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	89.1% (82.3%, 93.4%)	90.2% (83.7%, 94.2%)
	Month 12	85.2% (76.8%, 90.7%)	82.3% (72.1%, 89.0%)
	Month 18	81.3% (71.2%, 88.2%)	82.3% (72.1%, 89.0%)
	Month 24	78.4% (66.6%, 86.5%)	82.3% (72.1%, 89.0%)
	Month 30	74.3% (59.7%, 84.3%)	82.3% (72.1%, 89.0%)
	Month 36	74.3% (59.7%, 84.3%)	82.3% (72.1%, 89.0%)
	Hazard ratio[b] (95% CI)	1.05 (0.560, 1.983)	
	p-value of 2-sided stratified log-rank test	0.8684	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	6 (10.7%)	5 (11.1%)
	Censored	50 (89.3%)	40 (88.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	19.5 (12.1, NE)	NE (27.1, NE)
	50%	NE (17.9, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	96.3% (86.1%, 99.1%)	90.8% (77.3%, 96.5%)
	Month 12	96.3% (86.1%, 99.1%)	90.8% (77.3%, 96.5%)
	Month 18	76.8% (48.4%, 90.8%)	90.8% (77.3%, 96.5%)
	Month 24	68.3% (38.2%, 85.9%)	90.8% (77.3%, 96.5%)
	Month 30	68.3% (38.2%, 85.9%)	80.7% (50.3%, 93.5%)
	Month 36	68.3% (38.2%, 85.9%)	80.7% (50.3%, 93.5%)
	Hazard ratio[b] (95% CI)	0.76 (0.216, 2.671)	
	p-value of 2-sided stratified log-rank test	0.6664	
	p-value from Interaction Test[c]	0.8362	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	27 (20.3%)	7 (5.1%)
	Censored	106 (79.7%)	129 (94.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	34.5 (2.3, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	81.8% (74.1%, 87.4%)	94.7% (89.2%, 97.4%)
	Month 12	80.4% (72.1%, 86.4%)	94.7% (89.2%, 97.4%)
	Month 18	80.4% (72.1%, 86.4%)	94.7% (89.2%, 97.4%)
	Month 24	80.4% (72.1%, 86.4%)	94.7% (89.2%, 97.4%)
	Month 30	80.4% (72.1%, 86.4%)	94.7% (89.2%, 97.4%)
	Month 36	69.5% (51.4%, 82.0%)	94.7% (89.2%, 97.4%)
	Hazard ratio[b] (95% CI)	4.08 (1.764, 9.415)	
	p-value of 2-sided stratified log-rank test	0.0004	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	9 (16.1%)	3 (6.7%)
	Censored	47 (83.9%)	42 (93.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (0.4, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	83.9% (71.4%, 91.3%)	93.2% (80.4%, 97.8%)
	Month 12	83.9% (71.4%, 91.3%)	93.2% (80.4%, 97.8%)
	Month 18	83.9% (71.4%, 91.3%)	93.2% (80.4%, 97.8%)
	Month 24	83.9% (71.4%, 91.3%)	93.2% (80.4%, 97.8%)
	Month 30	83.9% (71.4%, 91.3%)	93.2% (80.4%, 97.8%)
	Month 36	83.9% (71.4%, 91.3%)	93.2% (80.4%, 97.8%)
	Hazard ratio[b] (95% CI)	2.73 (0.733, 10.138)	
	p-value of 2-sided stratified log-rank test	0.1193	
	p-value from Interaction Test[c]	0.6586	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Endocrinopathies

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	19 (14.3%)	5 (3.7%)
	Censored	114 (85.7%)	131 (96.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (11.5, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Endocrinopathies

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	88.1% (80.8%, 92.8%)	96.7% (91.5%, 98.8%)
	Month 12	83.9% (74.9%, 89.9%)	95.6% (89.6%, 98.2%)
	Month 18	81.7% (71.7%, 88.5%)	95.6% (89.6%, 98.2%)
	Month 24	77.4% (63.6%, 86.6%)	95.6% (89.6%, 98.2%)
	Month 30	77.4% (63.6%, 86.6%)	95.6% (89.6%, 98.2%)
	Month 36	77.4% (63.6%, 86.6%)	95.6% (89.6%, 98.2%)
	Hazard ratio[b] (95% CI)	3.89 (1.447, 10.444)	
	p-value of 2-sided stratified log-rank test	0.0037	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Endocrinopathies

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	9 (16.1%)	2 (4.4%)
	Censored	47 (83.9%)	43 (95.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (4.8, NE)	NE (11.1, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Endocrinopathies

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	87.7% (74.5%, 94.3%)	97.8% (85.3%, 99.7%)
	Month 12	76.7% (58.4%, 87.8%)	92.9% (72.1%, 98.3%)
	Month 18	76.7% (58.4%, 87.8%)	92.9% (72.1%, 98.3%)
	Month 24	76.7% (58.4%, 87.8%)	92.9% (72.1%, 98.3%)
	Month 30	76.7% (58.4%, 87.8%)	92.9% (72.1%, 98.3%)
	Month 36	76.7% (58.4%, 87.8%)	92.9% (72.1%, 98.3%)
	Hazard ratio[b] (95% CI)	4.18 (0.894, 19.523)	
	p-value of 2-sided stratified log-rank test	0.0490	
	p-value from Interaction Test[c]	0.8782	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Hepatic

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	10 (7.5%)	4 (2.9%)
	Censored	123 (92.5%)	132 (97.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Hepatic

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	94.3% (88.4%, 97.3%)	96.5% (90.9%, 98.7%)
	Month 12	92.0% (85.1%, 95.8%)	96.5% (90.9%, 98.7%)
	Month 18	89.6% (80.3%, 94.7%)	96.5% (90.9%, 98.7%)
	Month 24	89.6% (80.3%, 94.7%)	96.5% (90.9%, 98.7%)
	Month 30	89.6% (80.3%, 94.7%)	96.5% (90.9%, 98.7%)
	Month 36	89.6% (80.3%, 94.7%)	96.5% (90.9%, 98.7%)
	Hazard ratio[b] (95% CI)	3.26 (0.897, 11.877)	
	p-value of 2-sided stratified log-rank test	0.0574	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Hepatic

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	3 (5.4%)	1 (2.2%)
	Censored	53 (94.6%)	44 (97.8%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Hepatic

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	p-value from Interaction Test[c]	0.7560	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Gastrointestinal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	3 (2.3%)	1 (0.7%)
	Censored	130 (97.7%)	135 (99.3%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Gastrointestinal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	1 (2.2%)
	Censored	56 (100%)	44 (97.8%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pulmonary

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	3 (2.3%)	0
	Censored	130 (97.7%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pulmonary

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	2 (3.6%)	0
	Censored	54 (96.4%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Cardiovascular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	0	0
	Censored	133 (100%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Cardiovascular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	2 (3.6%)	0
	Censored	54 (96.4%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Ocular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	1 (0.8%)	0
	Censored	132 (99.2%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Ocular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	1 (1.8%)	0
	Censored	55 (98.2%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Nervous System

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	1 (0.8%)	0
	Censored	132 (99.2%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_4702_ttirae_reg.sas, Output: t_3_4702_ttirae_reg.rtf, Generated on: 12SEP2024 11:02,
Data Cutoff Date: 22SEP2023

Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Nervous System

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_4702_ttirae_reg.sas, Output: t_3_4702_ttirae_reg.rtf, Generated on: 12SEP2024 11:02,
Data Cutoff Date: 22SEP2023

Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pancreatitis

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	1 (0.8%)	0
	Censored	132 (99.2%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_4702_ttirae_reg.sas, Output: t_3_4702_ttirae_reg.rtf, Generated on: 12SEP2024 11:02,
Data Cutoff Date: 22SEP2023

Table 3.4702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pancreatitis

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_4702_ttirae_reg.sas, Output: t_3_4702_ttirae_reg.rtf, Generated on: 12SEP2024 11:02,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	45 (50.6%)	30 (34.5%)
	Censored	44 (49.4%)	57 (65.5%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.9 (0.7, 2.6)	1.4 (0.7, 11.3)
	50%	12.1 (4.1, NE)	NE (11.3, NE)
	75%	NE (33.6, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	56.6% (45.6%, 66.3%)	69.5% (58.5%, 78.1%)
	Month 12	51.1% (39.5%, 61.6%)	61.6% (47.7%, 72.8%)
	Month 18	45.1% (32.2%, 57.1%)	61.6% (47.7%, 72.8%)
	Month 24	40.6% (26.5%, 54.2%)	61.6% (47.7%, 72.8%)
	Month 30	40.6% (26.5%, 54.2%)	53.9% (34.7%, 69.7%)
	Month 36	32.5% (15.7%, 50.5%)	53.9% (34.7%, 69.7%)
	Hazard ratio[b] (95% CI)	1.42 (0.891, 2.261)	
	p-value of 2-sided stratified log-rank test	0.1341	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	21 (60.0%)	13 (43.3%)
	Censored	14 (40.0%)	17 (56.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.3 (0.0, 0.7)	0.8 (0.0, 8.3)
	50%	4.2 (0.4, NE)	NE (3.5, NE)
	75%	34.5 (15.7, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	48.6% (31.4%, 63.7%)	62.1% (41.7%, 77.1%)
	Month 12	45.1% (28.1%, 60.7%)	52.4% (31.6%, 69.6%)
	Month 18	33.8% (13.2%, 55.9%)	52.4% (31.6%, 69.6%)
	Month 24	33.8% (13.2%, 55.9%)	52.4% (31.6%, 69.6%)
	Month 30	33.8% (13.2%, 55.9%)	52.4% (31.6%, 69.6%)
	Month 36	0 (NE, NE)	52.4% (31.6%, 69.6%)
	Hazard ratio[b] (95% CI)	1.58 (0.773, 3.211)	
	p-value of 2-sided stratified log-rank test	0.2000	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	36 (55.4%)	22 (34.4%)
	Censored	29 (44.6%)	42 (65.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.7 (0.3, 3.3)	0.8 (0.5, 11.1)
	50%	6.8 (3.4, 17.9)	NE (11.1, NE)
	75%	NE (10.3, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	50.9% (37.5%, 62.8%)	67.7% (54.4%, 77.8%)
	Month 12	37.2% (23.5%, 50.9%)	62.0% (47.3%, 73.7%)
	Month 18	33.1% (19.2%, 47.6%)	62.0% (47.3%, 73.7%)
	Month 24	33.1% (19.2%, 47.6%)	62.0% (47.3%, 73.7%)
	Month 30	33.1% (19.2%, 47.6%)	62.0% (47.3%, 73.7%)
	Month 36	33.1% (19.2%, 47.6%)	62.0% (47.3%, 73.7%)
	Hazard ratio[b] (95% CI)	1.82 (1.069, 3.114)	
	p-value of 2-sided stratified log-rank test	0.0249	
	p-value from Interaction Test[c]	0.7989	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	37 (41.6%)	18 (20.7%)
	Censored	52 (58.4%)	69 (79.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	3.0 (0.8, 4.5)	11.3 (5.0, NE)
	50%	33.6 (9.5, NE)	NE (27.1, NE)
	75%	NE (33.6, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	63.6% (52.4%, 72.9%)	84.6% (74.9%, 90.8%)
	Month 12	57.9% (45.8%, 68.2%)	74.7% (60.5%, 84.4%)
	Month 18	51.6% (37.8%, 63.7%)	74.7% (60.5%, 84.4%)
	Month 24	51.6% (37.8%, 63.7%)	74.7% (60.5%, 84.4%)
	Month 30	51.6% (37.8%, 63.7%)	66.4% (44.4%, 81.3%)
	Month 36	43.0% (24.2%, 60.5%)	66.4% (44.4%, 81.3%)
	Hazard ratio[b] (95% CI)	2.06 (1.171, 3.633)	
	p-value of 2-sided stratified log-rank test	0.0104	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	16 (45.7%)	7 (23.3%)
	Censored	19 (54.3%)	23 (76.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.7 (0.2, 8.2)	11.1 (0.3, NE)
	50%	34.5 (2.4, NE)	NE (11.1, NE)
	75%	NE (34.5, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	62.4% (44.2%, 76.2%)	82.0% (61.6%, 92.2%)
	Month 12	53.8% (34.7%, 69.6%)	71.9% (48.9%, 85.9%)
	Month 18	53.8% (34.7%, 69.6%)	71.9% (48.9%, 85.9%)
	Month 24	53.8% (34.7%, 69.6%)	71.9% (48.9%, 85.9%)
	Month 30	53.8% (34.7%, 69.6%)	71.9% (48.9%, 85.9%)
	Month 36	26.9% (2.0%, 64.2%)	71.9% (48.9%, 85.9%)
	Hazard ratio[b] (95% CI)	2.51 (0.979, 6.423)	
	p-value of 2-sided stratified log-rank test	0.0470	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	33 (50.8%)	14 (21.9%)
	Censored	32 (49.2%)	50 (78.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	1.4 (0.4, 3.9)	11.1 (1.6, NE)
	50%	10.2 (3.9, NE)	NE (NE, NE)
	75%	NE (12.5, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
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Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	57.4% (43.9%, 68.8%)	80.2% (67.7%, 88.3%)
	Month 12	43.8% (29.3%, 57.4%)	74.8% (60.3%, 84.7%)
	Month 18	35.4% (20.4%, 50.7%)	74.8% (60.3%, 84.7%)
	Month 24	35.4% (20.4%, 50.7%)	74.8% (60.3%, 84.7%)
	Month 30	35.4% (20.4%, 50.7%)	74.8% (60.3%, 84.7%)
	Month 36	35.4% (20.4%, 50.7%)	74.8% (60.3%, 84.7%)
	Hazard ratio[b] (95% CI)	2.81 (1.497, 5.277)	
	p-value of 2-sided stratified log-rank test	0.0008	
	p-value from Interaction Test[c]	0.7679	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	15 (16.9%)	15 (17.2%)
	Censored	74 (83.1%)	72 (82.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (2.6, NE)	NE (2.1, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	84.2% (74.8%, 90.3%)	82.6% (72.8%, 89.1%)
	Month 12	84.2% (74.8%, 90.3%)	82.6% (72.8%, 89.1%)
	Month 18	84.2% (74.8%, 90.3%)	82.6% (72.8%, 89.1%)
	Month 24	78.2% (61.1%, 88.4%)	82.6% (72.8%, 89.1%)
	Month 30	78.2% (61.1%, 88.4%)	82.6% (72.8%, 89.1%)
	Month 36	78.2% (61.1%, 88.4%)	82.6% (72.8%, 89.1%)
	Hazard ratio[b] (95% CI)	0.94 (0.460, 1.928)	
	p-value of 2-sided stratified log-rank test	0.8793	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	7 (20.0%)	6 (20.0%)
	Censored	28 (80.0%)	24 (80.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	15.7 (0.0, NE)	NE (0.0, NE)
	50%	NE (15.7, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	82.9% (65.8%, 91.9%)	79.9% (60.5%, 90.4%)
	Month 12	82.9% (65.8%, 91.9%)	79.9% (60.5%, 90.4%)
	Month 18	72.5% (43.9%, 88.2%)	79.9% (60.5%, 90.4%)
	Month 24	72.5% (43.9%, 88.2%)	79.9% (60.5%, 90.4%)
	Month 30	72.5% (43.9%, 88.2%)	79.9% (60.5%, 90.4%)
	Month 36	72.5% (43.9%, 88.2%)	79.9% (60.5%, 90.4%)
	Hazard ratio[b] (95% CI)	0.97 (0.324, 2.886)	
	p-value of 2-sided stratified log-rank test	0.9500	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	11 (16.9%)	11 (17.2%)
	Censored	54 (83.1%)	53 (82.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (0.9, NE)	NE (0.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	82.6% (70.7%, 90.0%)	82.6% (70.8%, 90.0%)
	Month 12	82.6% (70.7%, 90.0%)	82.6% (70.8%, 90.0%)
	Month 18	82.6% (70.7%, 90.0%)	82.6% (70.8%, 90.0%)
	Month 24	82.6% (70.7%, 90.0%)	82.6% (70.8%, 90.0%)
	Month 30	82.6% (70.7%, 90.0%)	82.6% (70.8%, 90.0%)
	Month 36	82.6% (70.7%, 90.0%)	82.6% (70.8%, 90.0%)
	Hazard ratio[b] (95% CI)	0.99 (0.429, 2.283)	
	p-value of 2-sided stratified log-rank test	0.9876	
	p-value from Interaction Test[c]	0.9817	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	13 (14.6%)	10 (11.5%)
	Censored	76 (85.4%)	77 (88.5%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	19.8 (13.1, NE)	NE (11.3, NE)
	50%	NE (NE, NE)	NE (27.1, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	90.9% (82.7%, 95.4%)	91.7% (83.3%, 96.0%)
	Month 12	90.9% (82.7%, 95.4%)	85.2% (70.8%, 92.9%)
	Month 18	76.9% (59.3%, 87.6%)	85.2% (70.8%, 92.9%)
	Month 24	72.3% (53.2%, 84.7%)	85.2% (70.8%, 92.9%)
	Month 30	72.3% (53.2%, 84.7%)	75.8% (49.0%, 89.7%)
	Month 36	72.3% (53.2%, 84.7%)	75.8% (49.0%, 89.7%)
	Hazard ratio[b] (95% CI)	1.08 (0.471, 2.483)	
	p-value of 2-sided stratified log-rank test	0.8502	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	6 (17.1%)	5 (16.7%)
	Censored	29 (82.9%)	25 (83.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	19.5 (7.4, NE)	NE (2.8, NE)
	50%	NE (19.5, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	91.4% (75.7%, 97.2%)	89.9% (71.8%, 96.6%)
	Month 12	82.3% (61.4%, 92.5%)	79.5% (56.4%, 91.2%)
	Month 18	82.3% (61.4%, 92.5%)	79.5% (56.4%, 91.2%)
	Month 24	70.6% (38.5%, 88.0%)	79.5% (56.4%, 91.2%)
	Month 30	70.6% (38.5%, 88.0%)	79.5% (56.4%, 91.2%)
	Month 36	70.6% (38.5%, 88.0%)	79.5% (56.4%, 91.2%)
	Hazard ratio[b] (95% CI)	1.03 (0.313, 3.401)	
	p-value of 2-sided stratified log-rank test	0.9600	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	8 (12.3%)	8 (12.5%)
	Censored	57 (87.7%)	56 (87.5%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	29.3 (12.5, NE)	NE (NE, NE)
	50%	NE (29.3, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	91.6% (80.9%, 96.4%)	88.8% (77.9%, 94.5%)
	Month 12	88.4% (75.1%, 94.8%)	86.7% (75.1%, 93.2%)
	Month 18	84.2% (67.7%, 92.7%)	86.7% (75.1%, 93.2%)
	Month 24	84.2% (67.7%, 92.7%)	86.7% (75.1%, 93.2%)
	Month 30	74.8% (47.8%, 89.2%)	86.7% (75.1%, 93.2%)
	Month 36	74.8% (47.8%, 89.2%)	86.7% (75.1%, 93.2%)
	Hazard ratio[b] (95% CI)	0.96 (0.359, 2.547)	
	p-value of 2-sided stratified log-rank test	0.9283	
	p-value from Interaction Test[c]	0.9547	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	12 (13.5%)	4 (4.6%)
	Censored	77 (86.5%)	83 (95.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (33.6, NE)	NE (NE, NE)
	50%	NE (33.6, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	87.6% (78.7%, 92.9%)	95.2% (87.8%, 98.2%)
	Month 12	87.6% (78.7%, 92.9%)	95.2% (87.8%, 98.2%)
	Month 18	87.6% (78.7%, 92.9%)	95.2% (87.8%, 98.2%)
	Month 24	87.6% (78.7%, 92.9%)	95.2% (87.8%, 98.2%)
	Month 30	87.6% (78.7%, 92.9%)	95.2% (87.8%, 98.2%)
	Month 36	76.6% (47.5%, 90.9%)	95.2% (87.8%, 98.2%)
	Hazard ratio[b] (95% CI)	2.85 (0.913, 8.903)	
	p-value of 2-sided stratified log-rank test	0.0599	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	9 (25.7%)	1 (3.3%)
	Censored	26 (74.3%)	29 (96.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	34.5 (0.4, NE)	NE (NE, NE)
	50%	NE (34.5, NE)	NE (NE, NE)
	75%	NE (34.5, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	76.9% (59.1%, 87.7%)	96.7% (78.6%, 99.5%)
	Month 12	76.9% (59.1%, 87.7%)	96.7% (78.6%, 99.5%)
	Month 18	76.9% (59.1%, 87.7%)	96.7% (78.6%, 99.5%)
	Month 24	76.9% (59.1%, 87.7%)	96.7% (78.6%, 99.5%)
	Month 30	76.9% (59.1%, 87.7%)	96.7% (78.6%, 99.5%)
	Month 36	51.3% (10.2%, 82.3%)	96.7% (78.6%, 99.5%)
	Hazard ratio[b] (95% CI)	7.96 (1.009, 62.888)	
	p-value of 2-sided stratified log-rank test	0.0193	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	15 (23.1%)	5 (7.8%)
	Censored	50 (76.9%)	59 (92.2%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (0.4, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	78.4% (66.3%, 86.6%)	91.9% (81.7%, 96.6%)
	Month 12	75.2% (61.4%, 84.6%)	91.9% (81.7%, 96.6%)
	Month 18	75.2% (61.4%, 84.6%)	91.9% (81.7%, 96.6%)
	Month 24	75.2% (61.4%, 84.6%)	91.9% (81.7%, 96.6%)
	Month 30	75.2% (61.4%, 84.6%)	91.9% (81.7%, 96.6%)
	Month 36	75.2% (61.4%, 84.6%)	91.9% (81.7%, 96.6%)
	Hazard ratio[b] (95% CI)	3.40 (1.234, 9.350)	
	p-value of 2-sided stratified log-rank test	0.0123	
	p-value from Interaction Test[c]	0.6609	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	15 (16.9%)	4 (4.6%)
	Censored	74 (83.1%)	83 (95.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (5.5, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	84.7% (74.6%, 91.1%)	96.4% (89.1%, 98.8%)
	Month 12	78.2% (65.6%, 86.6%)	94.7% (86.2%, 98.0%)
	Month 18	78.2% (65.6%, 86.6%)	94.7% (86.2%, 98.0%)
	Month 24	78.2% (65.6%, 86.6%)	94.7% (86.2%, 98.0%)
	Month 30	78.2% (65.6%, 86.6%)	94.7% (86.2%, 98.0%)
	Month 36	78.2% (65.6%, 86.6%)	94.7% (86.2%, 98.0%)
	Hazard ratio[b] (95% CI)	3.63 (1.204, 10.949)	
	p-value of 2-sided stratified log-rank test	0.0143	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
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Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	3 (8.6%)	0
	Censored	32 (91.4%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	10 (15.4%)	3 (4.7%)
	Censored	55 (84.6%)	61 (95.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	21.4 (8.4, NE)	NE (NE, NE)
	50%	NE (21.4, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	90.8% (79.2%, 96.1%)	96.5% (86.6%, 99.1%)
	Month 12	82.1% (66.5%, 90.9%)	92.5% (76.3%, 97.8%)
	Month 18	77.8% (60.0%, 88.4%)	92.5% (76.3%, 97.8%)
	Month 24	68.1% (41.6%, 84.5%)	92.5% (76.3%, 97.8%)
	Month 30	68.1% (41.6%, 84.5%)	92.5% (76.3%, 97.8%)
	Month 36	68.1% (41.6%, 84.5%)	92.5% (76.3%, 97.8%)
	Hazard ratio[b] (95% CI)	3.44 (0.947, 12.516)	
	p-value of 2-sided stratified log-rank test	0.0456	
	p-value from Interaction Test[c]	0.9963	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	7 (7.9%)	1 (1.1%)
	Censored	82 (92.1%)	86 (98.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	92.5% (84.0%, 96.6%)	98.8% (91.9%, 99.8%)
	Month 12	90.3% (80.2%, 95.4%)	98.8% (91.9%, 99.8%)
	Month 18	90.3% (80.2%, 95.4%)	98.8% (91.9%, 99.8%)
	Month 24	90.3% (80.2%, 95.4%)	98.8% (91.9%, 99.8%)
	Month 30	90.3% (80.2%, 95.4%)	98.8% (91.9%, 99.8%)
	Month 36	90.3% (80.2%, 95.4%)	98.8% (91.9%, 99.8%)
	Hazard ratio[b] (95% CI)	6.88 (0.847, 55.965)	
	p-value of 2-sided stratified log-rank test	0.0360	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	1 (2.9%)	1 (3.3%)
	Censored	34 (97.1%)	29 (96.7%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	5 (7.7%)	3 (4.7%)
	Censored	60 (92.3%)	61 (95.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (16.7, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	95.2% (85.8%, 98.4%)	94.9% (84.8%, 98.3%)
	Month 12	93.0% (82.3%, 97.4%)	94.9% (84.8%, 98.3%)
	Month 18	88.4% (71.5%, 95.6%)	94.9% (84.8%, 98.3%)
	Month 24	88.4% (71.5%, 95.6%)	94.9% (84.8%, 98.3%)
	Month 30	88.4% (71.5%, 95.6%)	94.9% (84.8%, 98.3%)
	Month 36	88.4% (71.5%, 95.6%)	94.9% (84.8%, 98.3%)
	Hazard ratio[b] (95% CI)	1.62 (0.388, 6.797)	
	p-value of 2-sided stratified log-rank test	0.5030	
	p-value from Interaction Test[c]	0.4324	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
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Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Gastrointestinal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	1 (1.1%)	2 (2.3%)
	Censored	88 (98.9%)	85 (97.7%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Gastrointestinal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	2 (5.7%)	0
	Censored	33 (94.3%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Gastrointestinal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pulmonary

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	3 (3.4%)	0
	Censored	86 (96.6%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pulmonary

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	1 (2.9%)	0
	Censored	34 (97.1%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pulmonary

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	1 (1.5%)	0
	Censored	64 (98.5%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Cardiovascular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	2 (2.2%)	0
	Censored	87 (97.8%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Cardiovascular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Cardiovascular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Ocular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Ocular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
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Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Ocular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	2 (3.1%)	0
	Censored	63 (96.9%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
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Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Nervous System

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
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Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Nervous System

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Nervous System

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	1 (1.5%)	0
	Censored	64 (98.5%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pancreatitis

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pancreatitis

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	1 (2.9%)	0
	Censored	34 (97.1%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
Data Cutoff Date: 22SEP2023

Table 3.4802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events by irAE Category by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Category: Immune-mediated Pancreatitis

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_4802_ttirae_dis.sas, Output: t_3_4802_ttirae_dis.rtf, Generated on: 12SEP2024 11:04,
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	46 (47.9%)	26 (31.7%)
	Censored	50 (52.1%)	56 (68.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.8 (0.3, 3.0)	3.5 (0.7, 27.1)
	50%	10.2 (4.1, NE)	NE (27.1, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	55.1% (44.4%, 64.6%)	72.7% (61.5%, 81.1%)
	Month 12	48.7% (37.0%, 59.5%)	65.5% (52.3%, 75.8%)
	Month 18	44.7% (31.6%, 56.9%)	65.5% (52.3%, 75.8%)
	Month 24	44.7% (31.6%, 56.9%)	65.5% (52.3%, 75.8%)
	Month 30	44.7% (31.6%, 56.9%)	60.4% (44.5%, 73.1%)
	Month 36	44.7% (31.6%, 56.9%)	60.4% (44.5%, 73.1%)
	Hazard ratio[b] (95% CI)	1.64 (1.012, 2.671)	
	p-value of 2-sided stratified log-rank test	0.0392	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	43 (46.2%)	32 (32.3%)
	Censored	50 (53.8%)	67 (67.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	1.5 (0.7, 3.7)	2.8 (0.7, 11.1)
	50%	17.9 (6.9, NE)	NE (NE, NE)
	75%	NE (33.6, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	62.1% (51.2%, 71.3%)	68.8% (58.4%, 77.1%)
	Month 12	56.0% (44.6%, 66.0%)	63.2% (50.5%, 73.4%)
	Month 18	47.5% (34.3%, 59.6%)	63.2% (50.5%, 73.4%)
	Month 24	42.8% (28.2%, 56.6%)	63.2% (50.5%, 73.4%)
	Month 30	42.8% (28.2%, 56.6%)	63.2% (50.5%, 73.4%)
	Month 36	35.6% (18.9%, 52.8%)	63.2% (50.5%, 73.4%)
	Hazard ratio[b] (95% CI)	1.32 (0.825, 2.115)	
	p-value of 2-sided stratified log-rank test	0.2420	
	p-value from Interaction Test[c]	0.5567	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	35 (36.5%)	12 (14.6%)
	Censored	61 (63.5%)	70 (85.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	3.9 (1.4, 5.6)	NE (11.1, NE)
	50%	NE (9.6, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	66.0% (55.2%, 74.8%)	91.3% (82.5%, 95.7%)
	Month 12	57.4% (44.9%, 68.1%)	82.3% (69.3%, 90.2%)
	Month 18	57.4% (44.9%, 68.1%)	82.3% (69.3%, 90.2%)
	Month 24	57.4% (44.9%, 68.1%)	82.3% (69.3%, 90.2%)
	Month 30	57.4% (44.9%, 68.1%)	77.7% (61.4%, 87.8%)
	Month 36	57.4% (44.9%, 68.1%)	77.7% (61.4%, 87.8%)
	Hazard ratio[b] (95% CI)	2.95 (1.526, 5.714)	
	p-value of 2-sided stratified log-rank test	0.0008	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	39 (41.9%)	22 (22.2%)
	Censored	54 (58.1%)	77 (77.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	2.3 (0.7, 7.4)	11.1 (2.8, NE)
	50%	17.9 (11.1, NE)	NE (NE, NE)
	75%	NE (33.6, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	67.6% (56.8%, 76.3%)	79.0% (69.2%, 85.9%)
	Month 12	59.7% (48.0%, 69.6%)	73.8% (61.5%, 82.7%)
	Month 18	48.9% (35.1%, 61.3%)	73.8% (61.5%, 82.7%)
	Month 24	48.9% (35.1%, 61.3%)	73.8% (61.5%, 82.7%)
	Month 30	48.9% (35.1%, 61.3%)	73.8% (61.5%, 82.7%)
	Month 36	40.7% (22.7%, 58.0%)	73.8% (61.5%, 82.7%)
	Hazard ratio[b] (95% CI)	1.86 (1.085, 3.192)	
	p-value of 2-sided stratified log-rank test	0.0219	
	p-value from Interaction Test[c]	0.2870	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	19 (19.8%)	16 (19.5%)
	Censored	77 (80.2%)	66 (80.5%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (1.5, NE)	NE (0.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	81.1% (71.7%, 87.7%)	80.2% (69.7%, 87.4%)
	Month 12	81.1% (71.7%, 87.7%)	80.2% (69.7%, 87.4%)
	Month 18	76.9% (63.5%, 85.8%)	80.2% (69.7%, 87.4%)
	Month 24	76.9% (63.5%, 85.8%)	80.2% (69.7%, 87.4%)
	Month 30	76.9% (63.5%, 85.8%)	80.2% (69.7%, 87.4%)
	Month 36	76.9% (63.5%, 85.8%)	80.2% (69.7%, 87.4%)
	Hazard ratio[b] (95% CI)	1.00 (0.516, 1.959)	
	p-value of 2-sided stratified log-rank test	0.9810	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	10 (10.8%)	12 (12.1%)
	Censored	83 (89.2%)	87 (87.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (22.6, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	90.2% (82.0%, 94.8%)	87.8% (79.5%, 92.9%)
	Month 12	90.2% (82.0%, 94.8%)	87.8% (79.5%, 92.9%)
	Month 18	90.2% (82.0%, 94.8%)	87.8% (79.5%, 92.9%)
	Month 24	84.5% (67.4%, 93.1%)	87.8% (79.5%, 92.9%)
	Month 30	84.5% (67.4%, 93.1%)	87.8% (79.5%, 92.9%)
	Month 36	84.5% (67.4%, 93.1%)	87.8% (79.5%, 92.9%)
	Hazard ratio[b] (95% CI)	0.83 (0.356, 1.921)	
	p-value of 2-sided stratified log-rank test	0.6610	
	p-value from Interaction Test[c]	0.7852	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	10 (10.4%)	9 (11.0%)
	Censored	86 (89.6%)	73 (89.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (17.9, NE)	NE (27.1, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	93.6% (86.2%, 97.1%)	93.7% (85.6%, 97.3%)
	Month 12	93.6% (86.2%, 97.1%)	87.4% (75.5%, 93.7%)
	Month 18	86.5% (71.5%, 94.0%)	87.4% (75.5%, 93.7%)
	Month 24	82.2% (64.5%, 91.6%)	87.4% (75.5%, 93.7%)
	Month 30	76.3% (55.0%, 88.5%)	82.8% (66.6%, 91.6%)
	Month 36	76.3% (55.0%, 88.5%)	82.8% (66.6%, 91.6%)
	Hazard ratio[b] (95% CI)	0.87 (0.353, 2.150)	
	p-value of 2-sided stratified log-rank test	0.7625	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	17 (18.3%)	14 (14.1%)
	Censored	76 (81.7%)	85 (85.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	13.8 (11.1, NE)	NE (11.1, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	88.8% (80.2%, 93.8%)	87.6% (79.2%, 92.8%)
	Month 12	83.1% (72.0%, 90.1%)	82.4% (70.3%, 89.9%)
	Month 18	74.7% (60.1%, 84.5%)	82.4% (70.3%, 89.9%)
	Month 24	70.3% (53.6%, 81.9%)	82.4% (70.3%, 89.9%)
	Month 30	70.3% (53.6%, 81.9%)	82.4% (70.3%, 89.9%)
	Month 36	70.3% (53.6%, 81.9%)	82.4% (70.3%, 89.9%)
	Hazard ratio[b] (95% CI)	1.13 (0.552, 2.307)	
	p-value of 2-sided stratified log-rank test	0.7369	
	p-value from Interaction Test[c]	0.6946	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects
irAE Category: Immune-mediated Skin Adverse Reactions

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	12 (12.5%)	4 (4.9%)
	Censored	84 (87.5%)	78 (95.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	87.5% (79.0%, 92.7%)	94.9% (87.1%, 98.1%)
	Month 12	87.5% (79.0%, 92.7%)	94.9% (87.1%, 98.1%)
	Month 18	87.5% (79.0%, 92.7%)	94.9% (87.1%, 98.1%)
	Month 24	87.5% (79.0%, 92.7%)	94.9% (87.1%, 98.1%)
	Month 30	87.5% (79.0%, 92.7%)	94.9% (87.1%, 98.1%)
	Month 36	87.5% (79.0%, 92.7%)	94.9% (87.1%, 98.1%)
	Hazard ratio[b] (95% CI)	2.61 (0.841, 8.092)	
	p-value of 2-sided stratified log-rank test	0.0852	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects
irAE Category: Immune-mediated Skin Adverse Reactions

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	15 (16.1%)	3 (3.0%)
	Censored	78 (83.9%)	96 (97.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	33.6 (33.6, NE)	NE (NE, NE)
	50%	NE (33.6, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	84.5% (75.3%, 90.6%)	96.9% (90.6%, 99.0%)
	Month 12	84.5% (75.3%, 90.6%)	96.9% (90.6%, 99.0%)
	Month 18	84.5% (75.3%, 90.6%)	96.9% (90.6%, 99.0%)
	Month 24	84.5% (75.3%, 90.6%)	96.9% (90.6%, 99.0%)
	Month 30	84.5% (75.3%, 90.6%)	96.9% (90.6%, 99.0%)
	Month 36	74.0% (47.0%, 88.7%)	96.9% (90.6%, 99.0%)
	Hazard ratio[b] (95% CI)	5.49 (1.572, 19.178)	
	p-value of 2-sided stratified log-rank test	0.0028	
	p-value from Interaction Test[c]	0.3836	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	15 (15.6%)	1 (1.2%)
	Censored	81 (84.4%)	81 (98.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (8.4, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	87.5% (78.4%, 92.9%)	100% (100%, 100%)
	Month 12	78.5% (65.7%, 87.0%)	97.3% (82.3%, 99.6%)
	Month 18	78.5% (65.7%, 87.0%)	97.3% (82.3%, 99.6%)
	Month 24	78.5% (65.7%, 87.0%)	97.3% (82.3%, 99.6%)
	Month 30	78.5% (65.7%, 87.0%)	97.3% (82.3%, 99.6%)
	Month 36	78.5% (65.7%, 87.0%)	97.3% (82.3%, 99.6%)
	Hazard ratio[b] (95% CI)	13.95 (1.841, 105.761)	
	p-value of 2-sided stratified log-rank test	0.0008	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	11 (11.8%)	4 (4.0%)
	Censored	82 (88.2%)	95 (96.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (13.8, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	91.2% (82.5%, 95.7%)	95.6% (88.8%, 98.3%)
	Month 12	87.9% (77.7%, 93.6%)	95.6% (88.8%, 98.3%)
	Month 18	84.7% (72.2%, 91.9%)	95.6% (88.8%, 98.3%)
	Month 24	78.7% (59.7%, 89.4%)	95.6% (88.8%, 98.3%)
	Month 30	78.7% (59.7%, 89.4%)	95.6% (88.8%, 98.3%)
	Month 36	78.7% (59.7%, 89.4%)	95.6% (88.8%, 98.3%)
	Hazard ratio[b] (95% CI)	2.83 (0.897, 8.936)	
	p-value of 2-sided stratified log-rank test	0.0639	
	p-value from Interaction Test[c]	0.1629	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	6 (6.3%)	2 (2.4%)
	Censored	90 (93.8%)	80 (97.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	94.2% (86.4%, 97.5%)	97.5% (90.4%, 99.4%)
	Month 12	92.1% (82.8%, 96.5%)	97.5% (90.4%, 99.4%)
	Month 18	92.1% (82.8%, 96.5%)	97.5% (90.4%, 99.4%)
	Month 24	92.1% (82.8%, 96.5%)	97.5% (90.4%, 99.4%)
	Month 30	92.1% (82.8%, 96.5%)	97.5% (90.4%, 99.4%)
	Month 36	92.1% (82.8%, 96.5%)	97.5% (90.4%, 99.4%)
	Hazard ratio[b] (95% CI)	2.48 (0.500, 12.314)	
	p-value of 2-sided stratified log-rank test	0.2499	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	3 (3.2%)	1 (1.0%)
	Censored	90 (96.8%)	98 (99.0%)
	p-value from Interaction Test[c]	0.8982	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	3 (3.1%)	0
	Censored	93 (96.9%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	2 (2.2%)	0
	Censored	91 (97.8%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
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Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	1 (1.0%)	0
	Censored	95 (99.0%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
Data Cutoff Date: 22SEP2023

Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	2 (2.2%)	1 (1.0%)
	Censored	91 (97.8%)	98 (99.0%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
Data Cutoff Date: 22SEP2023

Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
Data Cutoff Date: 22SEP2023

Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	2 (2.2%)	0
	Censored	91 (97.8%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
Data Cutoff Date: 22SEP2023

Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	1 (1.0%)	0
	Censored	95 (99.0%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
Data Cutoff Date: 22SEP2023

Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
Data Cutoff Date: 22SEP2023

Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
Data Cutoff Date: 22SEP2023

Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
Data Cutoff Date: 22SEP2023

Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
Data Cutoff Date: 22SEP2023

Table 3.5002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5002_ttirae_le2_age.sas, Output: t_3_5002_ttirae_le2_age.rtf, Generated on: 20SEP2024 09:34,
Data Cutoff Date: 22SEP2023

Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	65 (48.9%)	46 (33.8%)
	Censored	68 (51.1%)	90 (66.2%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.9 (0.4, 2.2)	1.3 (0.7, 6.0)
	50%	13.8 (4.1, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	55.4% (46.4%, 63.5%)	68.0% (59.1%, 75.3%)
	Month 12	50.8% (41.5%, 59.4%)	60.9% (50.2%, 70.0%)
	Month 18	46.6% (36.5%, 56.2%)	60.9% (50.2%, 70.0%)
	Month 24	46.6% (36.5%, 56.2%)	60.9% (50.2%, 70.0%)
	Month 30	46.6% (36.5%, 56.2%)	60.9% (50.2%, 70.0%)
	Month 36	41.5% (28.4%, 54.0%)	60.9% (50.2%, 70.0%)
	Hazard ratio[b] (95% CI)	1.42 (0.964, 2.080)	
	p-value of 2-sided stratified log-rank test	0.0699	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	24 (42.9%)	12 (26.7%)
	Censored	32 (57.1%)	33 (73.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	2.6 (0.7, 7.9)	11.1 (0.5, NE)
	50%	12.1 (6.9, NE)	NE (27.1, NE)
	75%	NE (17.9, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	66.3% (51.8%, 77.3%)	77.4% (62.1%, 87.2%)
	Month 12	55.3% (38.2%, 69.3%)	72.6% (54.6%, 84.4%)
	Month 18	40.9% (20.5%, 60.5%)	72.6% (54.6%, 84.4%)
	Month 24	30.7% (10.5%, 53.9%)	72.6% (54.6%, 84.4%)
	Month 30	30.7% (10.5%, 53.9%)	62.2% (36.0%, 80.3%)
	Month 36	NE (NE, NE)	62.2% (36.0%, 80.3%)
	Hazard ratio[b] (95% CI)	1.80 (0.869, 3.724)	
	p-value of 2-sided stratified log-rank test	0.1087	
	p-value from Interaction Test[c]	0.6484	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	54 (40.6%)	25 (18.4%)
	Censored	79 (59.4%)	111 (81.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	2.4 (1.2, 4.4)	NE (8.3, NE)
	50%	33.6 (10.2, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	64.9% (55.9%, 72.5%)	84.5% (76.9%, 89.8%)
	Month 12	57.7% (48.0%, 66.3%)	76.7% (66.3%, 84.2%)
	Month 18	54.0% (43.5%, 63.3%)	76.7% (66.3%, 84.2%)
	Month 24	54.0% (43.5%, 63.3%)	76.7% (66.3%, 84.2%)
	Month 30	54.0% (43.5%, 63.3%)	76.7% (66.3%, 84.2%)
	Month 36	48.6% (34.7%, 61.2%)	76.7% (66.3%, 84.2%)
	Hazard ratio[b] (95% CI)	2.37 (1.460, 3.846)	
	p-value of 2-sided stratified log-rank test	0.0003	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	20 (35.7%)	9 (20.0%)
	Censored	36 (64.3%)	36 (80.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	4.2 (0.9, 9.5)	27.1 (3.5, NE)
	50%	17.9 (7.9, NE)	NE (27.1, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	71.6% (57.3%, 81.9%)	84.0% (69.3%, 92.1%)
	Month 12	60.4% (42.8%, 74.1%)	79.3% (61.5%, 89.5%)
	Month 18	46.6% (25.2%, 65.5%)	79.3% (61.5%, 89.5%)
	Month 24	46.6% (25.2%, 65.5%)	79.3% (61.5%, 89.5%)
	Month 30	46.6% (25.2%, 65.5%)	69.4% (42.3%, 85.7%)
	Month 36	46.6% (25.2%, 65.5%)	69.4% (42.3%, 85.7%)
	Hazard ratio[b] (95% CI)	1.89 (0.843, 4.243)	
	p-value of 2-sided stratified log-rank test	0.1164	
	p-value from Interaction Test[c]	0.7974	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	23 (17.3%)	24 (17.6%)
	Censored	110 (82.7%)	112 (82.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (15.7, NE)	NE (3.5, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	83.3% (75.8%, 88.7%)	82.1% (74.4%, 87.6%)
	Month 12	83.3% (75.8%, 88.7%)	82.1% (74.4%, 87.6%)
	Month 18	80.9% (71.6%, 87.4%)	82.1% (74.4%, 87.6%)
	Month 24	80.9% (71.6%, 87.4%)	82.1% (74.4%, 87.6%)
	Month 30	80.9% (71.6%, 87.4%)	82.1% (74.4%, 87.6%)
	Month 36	80.9% (71.6%, 87.4%)	82.1% (74.4%, 87.6%)
	Hazard ratio[b] (95% CI)	0.94 (0.531, 1.673)	
	p-value of 2-sided stratified log-rank test	0.8444	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	6 (10.7%)	4 (8.9%)
	Censored	50 (89.3%)	41 (91.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (22.6, NE)	NE (NE, NE)
	50%	NE (22.6, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	90.9% (79.4%, 96.1%)	91.1% (78.0%, 96.6%)
	Month 12	90.9% (79.4%, 96.1%)	91.1% (78.0%, 96.6%)
	Month 18	90.9% (79.4%, 96.1%)	91.1% (78.0%, 96.6%)
	Month 24	79.5% (46.7%, 93.3%)	91.1% (78.0%, 96.6%)
	Month 30	79.5% (46.7%, 93.3%)	91.1% (78.0%, 96.6%)
	Month 36	79.5% (46.7%, 93.3%)	91.1% (78.0%, 96.6%)
	Hazard ratio[b] (95% CI)	1.12 (0.310, 4.050)	
	p-value of 2-sided stratified log-rank test	0.8612	
	p-value from Interaction Test[c]	0.7288	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	21 (15.8%)	18 (13.2%)
	Censored	112 (84.2%)	118 (86.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	29.3 (12.5, NE)	NE (11.3, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	89.1% (82.3%, 93.4%)	90.2% (83.7%, 94.2%)
	Month 12	85.2% (76.8%, 90.7%)	82.3% (72.1%, 89.0%)
	Month 18	81.3% (71.2%, 88.2%)	82.3% (72.1%, 89.0%)
	Month 24	78.4% (66.6%, 86.5%)	82.3% (72.1%, 89.0%)
	Month 30	74.3% (59.7%, 84.3%)	82.3% (72.1%, 89.0%)
	Month 36	74.3% (59.7%, 84.3%)	82.3% (72.1%, 89.0%)
	Hazard ratio[b] (95% CI)	1.05 (0.560, 1.983)	
	p-value of 2-sided stratified log-rank test	0.8684	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Data Cutoff Date: 22SEP2023

Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	6 (10.7%)	5 (11.1%)
	Censored	50 (89.3%)	40 (88.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	19.5 (12.1, NE)	NE (27.1, NE)
	50%	NE (17.9, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	96.3% (86.1%, 99.1%)	90.8% (77.3%, 96.5%)
	Month 12	96.3% (86.1%, 99.1%)	90.8% (77.3%, 96.5%)
	Month 18	76.8% (48.4%, 90.8%)	90.8% (77.3%, 96.5%)
	Month 24	68.3% (38.2%, 85.9%)	90.8% (77.3%, 96.5%)
	Month 30	68.3% (38.2%, 85.9%)	80.7% (50.3%, 93.5%)
	Month 36	68.3% (38.2%, 85.9%)	80.7% (50.3%, 93.5%)
	Hazard ratio[b] (95% CI)	0.76 (0.216, 2.671)	
	p-value of 2-sided stratified log-rank test	0.6664	
	p-value from Interaction Test[c]	0.8362	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects
irAE Category: Immune-mediated Skin Adverse Reactions

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	20 (15.0%)	4 (2.9%)
	Censored	113 (85.0%)	132 (97.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (33.6, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects
irAE Category: Immune-mediated Skin Adverse Reactions

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	85.5% (78.2%, 90.5%)	96.9% (92.1%, 98.8%)
	Month 12	85.5% (78.2%, 90.5%)	96.9% (92.1%, 98.8%)
	Month 18	85.5% (78.2%, 90.5%)	96.9% (92.1%, 98.8%)
	Month 24	85.5% (78.2%, 90.5%)	96.9% (92.1%, 98.8%)
	Month 30	85.5% (78.2%, 90.5%)	96.9% (92.1%, 98.8%)
	Month 36	80.2% (65.3%, 89.2%)	96.9% (92.1%, 98.8%)
	Hazard ratio[b] (95% CI)	5.25 (1.781, 15.468)	
	p-value of 2-sided stratified log-rank test	0.0008	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects
irAE Category: Immune-mediated Skin Adverse Reactions

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	7 (12.5%)	3 (6.7%)
	Censored	49 (87.5%)	42 (93.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects
irAE Category: Immune-mediated Skin Adverse Reactions

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	87.5% (75.6%, 93.8%)	93.2% (80.4%, 97.8%)
	Month 12	87.5% (75.6%, 93.8%)	93.2% (80.4%, 97.8%)
	Month 18	87.5% (75.6%, 93.8%)	93.2% (80.4%, 97.8%)
	Month 24	87.5% (75.6%, 93.8%)	93.2% (80.4%, 97.8%)
	Month 30	87.5% (75.6%, 93.8%)	93.2% (80.4%, 97.8%)
	Month 36	87.5% (75.6%, 93.8%)	93.2% (80.4%, 97.8%)
	Hazard ratio[b] (95% CI)	2.11 (0.540, 8.234)	
	p-value of 2-sided stratified log-rank test	0.2718	
	p-value from Interaction Test[c]	0.2985	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	17 (12.8%)	3 (2.2%)
	Censored	116 (87.2%)	133 (97.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (13.8, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	89.9% (82.9%, 94.2%)	97.5% (92.3%, 99.2%)
	Month 12	85.6% (76.9%, 91.3%)	97.5% (92.3%, 99.2%)
	Month 18	83.5% (73.6%, 89.9%)	97.5% (92.3%, 99.2%)
	Month 24	79.3% (65.6%, 88.1%)	97.5% (92.3%, 99.2%)
	Month 30	79.3% (65.6%, 88.1%)	97.5% (92.3%, 99.2%)
	Month 36	79.3% (65.6%, 88.1%)	97.5% (92.3%, 99.2%)
	Hazard ratio[b] (95% CI)	5.76 (1.683, 19.736)	
	p-value of 2-sided stratified log-rank test	0.0016	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	9 (16.1%)	2 (4.4%)
	Censored	47 (83.9%)	43 (95.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (4.8, NE)	NE (11.1, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	87.7% (74.5%, 94.3%)	97.8% (85.3%, 99.7%)
	Month 12	76.7% (58.4%, 87.8%)	92.9% (72.1%, 98.3%)
	Month 18	76.7% (58.4%, 87.8%)	92.9% (72.1%, 98.3%)
	Month 24	76.7% (58.4%, 87.8%)	92.9% (72.1%, 98.3%)
	Month 30	76.7% (58.4%, 87.8%)	92.9% (72.1%, 98.3%)
	Month 36	76.7% (58.4%, 87.8%)	92.9% (72.1%, 98.3%)
	Hazard ratio[b] (95% CI)	4.18 (0.894, 19.523)	
	p-value of 2-sided stratified log-rank test	0.0490	
	p-value from Interaction Test[c]	0.8055	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	8 (6.0%)	3 (2.2%)
	Censored	125 (94.0%)	133 (97.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	95.1% (89.4%, 97.8%)	97.5% (92.4%, 99.2%)
	Month 12	92.7% (85.7%, 96.3%)	97.5% (92.4%, 99.2%)
	Month 18	92.7% (85.7%, 96.3%)	97.5% (92.4%, 99.2%)
	Month 24	92.7% (85.7%, 96.3%)	97.5% (92.4%, 99.2%)
	Month 30	92.7% (85.7%, 96.3%)	97.5% (92.4%, 99.2%)
	Month 36	92.7% (85.7%, 96.3%)	97.5% (92.4%, 99.2%)
	Hazard ratio[b] (95% CI)	4.07 (0.863, 19.173)	
	p-value of 2-sided stratified log-rank test	0.0546	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	1 (1.8%)	0
	Censored	55 (98.2%)	45 (100%)
	p-value from Interaction Test[c]	0.9950	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	3 (2.3%)	0
	Censored	130 (97.7%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	2 (3.6%)	0
	Censored	54 (96.4%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	3 (2.3%)	1 (0.7%)
	Censored	130 (97.7%)	135 (99.3%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	1 (0.8%)	0
	Censored	132 (99.2%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	1 (1.8%)	0
	Censored	55 (98.2%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	0	0
	Censored	133 (100%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	1 (1.8%)	0
	Censored	55 (98.2%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	0	0
	Censored	133 (100%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	0	0
	Censored	133 (100%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.5102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5102_ttirae_le2_reg.sas, Output: t_3_5102_ttirae_le2_reg.rtf, Generated on: 11SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	43 (48.3%)	25 (28.7%)
	Censored	46 (51.7%)	62 (71.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	1.4 (0.7, 3.0)	3.8 (0.7, NE)
	50%	13.8 (4.2, NE)	NE (27.1, NE)
	75%	NE (33.6, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
Data Cutoff Date: 22SEP2023

Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	58.7% (47.5%, 68.2%)	72.9% (62.0%, 81.1%)
	Month 12	53.0% (41.2%, 63.4%)	68.3% (54.1%, 79.0%)
	Month 18	46.7% (33.5%, 58.9%)	68.3% (54.1%, 79.0%)
	Month 24	42.0% (27.5%, 55.9%)	68.3% (54.1%, 79.0%)
	Month 30	42.0% (27.5%, 55.9%)	59.8% (38.4%, 75.8%)
	Month 36	33.6% (16.2%, 52.0%)	59.8% (38.4%, 75.8%)
	Hazard ratio[b] (95% CI)	1.64 (0.999, 2.699)	
	p-value of 2-sided stratified log-rank test	0.0452	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
Data Cutoff Date: 22SEP2023

Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	17 (48.6%)	13 (43.3%)
	Censored	18 (51.4%)	17 (56.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.4 (0.0, 2.3)	0.8 (0.0, 8.3)
	50%	15.7 (1.4, NE)	NE (3.5, NE)
	75%	NE (15.7, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
Data Cutoff Date: 22SEP2023

Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	53.8% (36.0%, 68.6%)	62.1% (41.7%, 77.1%)
	Month 12	53.8% (36.0%, 68.6%)	52.4% (31.6%, 69.6%)
	Month 18	43.0% (20.3%, 64.0%)	52.4% (31.6%, 69.6%)
	Month 24	43.0% (20.3%, 64.0%)	52.4% (31.6%, 69.6%)
	Month 30	43.0% (20.3%, 64.0%)	52.4% (31.6%, 69.6%)
	Month 36	43.0% (20.3%, 64.0%)	52.4% (31.6%, 69.6%)
	Hazard ratio[b] (95% CI)	1.22 (0.580, 2.556)	
	p-value of 2-sided stratified log-rank test	0.5940	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
Data Cutoff Date: 22SEP2023

Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	29 (44.6%)	20 (31.3%)
	Censored	36 (55.4%)	44 (68.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	2.2 (0.4, 4.8)	1.8 (0.7, NE)
	50%	10.2 (4.8, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
Data Cutoff Date: 22SEP2023

Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	60.8% (47.3%, 71.9%)	71.1% (58.1%, 80.7%)
	Month 12	49.8% (35.0%, 62.9%)	65.2% (50.3%, 76.7%)
	Month 18	44.8% (28.8%, 59.6%)	65.2% (50.3%, 76.7%)
	Month 24	44.8% (28.8%, 59.6%)	65.2% (50.3%, 76.7%)
	Month 30	44.8% (28.8%, 59.6%)	65.2% (50.3%, 76.7%)
	Month 36	44.8% (28.8%, 59.6%)	65.2% (50.3%, 76.7%)
	Hazard ratio[b] (95% CI)	1.46 (0.824, 2.600)	
	p-value of 2-sided stratified log-rank test	0.1873	
	p-value from Interaction Test[c]	0.8460	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
Data Cutoff Date: 22SEP2023

Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	36 (40.4%)	15 (17.2%)
	Censored	53 (59.6%)	72 (82.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	3.6 (0.8, 5.6)	27.1 (8.7, NE)
	50%	33.6 (9.5, NE)	NE (27.1, NE)
	75%	NE (33.6, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
Data Cutoff Date: 22SEP2023

Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	64.8% (53.5%, 74.0%)	85.7% (76.2%, 91.7%)
	Month 12	58.9% (46.8%, 69.2%)	79.3% (65.1%, 88.2%)
	Month 18	52.5% (38.6%, 64.6%)	79.3% (65.1%, 88.2%)
	Month 24	52.5% (38.6%, 64.6%)	79.3% (65.1%, 88.2%)
	Month 30	52.5% (38.6%, 64.6%)	70.5% (46.8%, 85.1%)
	Month 36	43.7% (24.6%, 61.4%)	70.5% (46.8%, 85.1%)
	Hazard ratio[b] (95% CI)	2.43 (1.325, 4.446)	
	p-value of 2-sided stratified log-rank test	0.0030	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
Data Cutoff Date: 22SEP2023

Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	12 (34.3%)	7 (23.3%)
	Censored	23 (65.7%)	23 (76.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	2.3 (0.3, NE)	11.1 (0.3, NE)
	50%	NE (4.2, NE)	NE (11.1, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
Data Cutoff Date: 22SEP2023

Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	67.6% (49.1%, 80.6%)	82.0% (61.6%, 92.2%)
	Month 12	62.4% (42.5%, 77.1%)	71.9% (48.9%, 85.9%)
	Month 18	62.4% (42.5%, 77.1%)	71.9% (48.9%, 85.9%)
	Month 24	62.4% (42.5%, 77.1%)	71.9% (48.9%, 85.9%)
	Month 30	62.4% (42.5%, 77.1%)	71.9% (48.9%, 85.9%)
	Month 36	62.4% (42.5%, 77.1%)	71.9% (48.9%, 85.9%)
	Hazard ratio[b] (95% CI)	1.77 (0.662, 4.713)	
	p-value of 2-sided stratified log-rank test	0.2477	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
Data Cutoff Date: 22SEP2023

Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	26 (40.0%)	12 (18.8%)
	Censored	39 (60.0%)	52 (81.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	3.9 (0.9, 8.4)	NE (3.5, NE)
	50%	17.9 (8.4, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
Data Cutoff Date: 22SEP2023

Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	69.1% (55.7%, 79.1%)	83.7% (71.8%, 90.9%)
	Month 12	55.2% (39.7%, 68.2%)	78.1% (63.6%, 87.3%)
	Month 18	45.9% (28.6%, 61.5%)	78.1% (63.6%, 87.3%)
	Month 24	45.9% (28.6%, 61.5%)	78.1% (63.6%, 87.3%)
	Month 30	45.9% (28.6%, 61.5%)	78.1% (63.6%, 87.3%)
	Month 36	45.9% (28.6%, 61.5%)	78.1% (63.6%, 87.3%)
	Hazard ratio[b] (95% CI)	2.34 (1.173, 4.655)	
	p-value of 2-sided stratified log-rank test	0.0132	
	p-value from Interaction Test[c]	0.7877	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
Data Cutoff Date: 22SEP2023

Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	12 (13.5%)	13 (14.9%)
	Censored	77 (86.5%)	74 (85.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (22.6, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	87.6% (78.7%, 92.9%)	84.9% (75.4%, 90.9%)
	Month 12	87.6% (78.7%, 92.9%)	84.9% (75.4%, 90.9%)
	Month 18	87.6% (78.7%, 92.9%)	84.9% (75.4%, 90.9%)
	Month 24	81.3% (63.2%, 91.1%)	84.9% (75.4%, 90.9%)
	Month 30	81.3% (63.2%, 91.1%)	84.9% (75.4%, 90.9%)
	Month 36	81.3% (63.2%, 91.1%)	84.9% (75.4%, 90.9%)
	Hazard ratio[b] (95% CI)	0.86 (0.393, 1.894)	
	p-value of 2-sided stratified log-rank test	0.7265	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	7 (20.0%)	6 (20.0%)
	Censored	28 (80.0%)	24 (80.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	15.7 (0.0, NE)	NE (0.0, NE)
	50%	NE (15.7, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	82.9% (65.8%, 91.9%)	79.9% (60.5%, 90.4%)
	Month 12	82.9% (65.8%, 91.9%)	79.9% (60.5%, 90.4%)
	Month 18	72.5% (43.9%, 88.2%)	79.9% (60.5%, 90.4%)
	Month 24	72.5% (43.9%, 88.2%)	79.9% (60.5%, 90.4%)
	Month 30	72.5% (43.9%, 88.2%)	79.9% (60.5%, 90.4%)
	Month 36	72.5% (43.9%, 88.2%)	79.9% (60.5%, 90.4%)
	Hazard ratio[b] (95% CI)	0.97 (0.324, 2.886)	
	p-value of 2-sided stratified log-rank test	0.9500	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	10 (15.4%)	9 (14.1%)
	Censored	55 (84.6%)	55 (85.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (1.4, NE)	NE (0.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	84.1% (72.5%, 91.2%)	85.8% (74.5%, 92.3%)
	Month 12	84.1% (72.5%, 91.2%)	85.8% (74.5%, 92.3%)
	Month 18	84.1% (72.5%, 91.2%)	85.8% (74.5%, 92.3%)
	Month 24	84.1% (72.5%, 91.2%)	85.8% (74.5%, 92.3%)
	Month 30	84.1% (72.5%, 91.2%)	85.8% (74.5%, 92.3%)
	Month 36	84.1% (72.5%, 91.2%)	85.8% (74.5%, 92.3%)
	Hazard ratio[b] (95% CI)	1.11 (0.449, 2.722)	
	p-value of 2-sided stratified log-rank test	0.8208	
	p-value from Interaction Test[c]	0.9297	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	13 (14.6%)	10 (11.5%)
	Censored	76 (85.4%)	77 (88.5%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	19.8 (13.1, NE)	NE (11.3, NE)
	50%	NE (NE, NE)	NE (27.1, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	90.9% (82.7%, 95.4%)	91.7% (83.3%, 96.0%)
	Month 12	90.9% (82.7%, 95.4%)	85.2% (70.8%, 92.9%)
	Month 18	76.9% (59.3%, 87.6%)	85.2% (70.8%, 92.9%)
	Month 24	72.3% (53.2%, 84.7%)	85.2% (70.8%, 92.9%)
	Month 30	72.3% (53.2%, 84.7%)	75.8% (49.0%, 89.7%)
	Month 36	72.3% (53.2%, 84.7%)	75.8% (49.0%, 89.7%)
	Hazard ratio[b] (95% CI)	1.08 (0.471, 2.483)	
	p-value of 2-sided stratified log-rank test	0.8502	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	6 (17.1%)	5 (16.7%)
	Censored	29 (82.9%)	25 (83.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	19.5 (7.4, NE)	NE (2.8, NE)
	50%	NE (19.5, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	91.4% (75.7%, 97.2%)	89.9% (71.8%, 96.6%)
	Month 12	82.3% (61.4%, 92.5%)	79.5% (56.4%, 91.2%)
	Month 18	82.3% (61.4%, 92.5%)	79.5% (56.4%, 91.2%)
	Month 24	70.6% (38.5%, 88.0%)	79.5% (56.4%, 91.2%)
	Month 30	70.6% (38.5%, 88.0%)	79.5% (56.4%, 91.2%)
	Month 36	70.6% (38.5%, 88.0%)	79.5% (56.4%, 91.2%)
	Hazard ratio[b] (95% CI)	1.03 (0.313, 3.401)	
	p-value of 2-sided stratified log-rank test	0.9600	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	8 (12.3%)	8 (12.5%)
	Censored	57 (87.7%)	56 (87.5%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	29.3 (12.5, NE)	NE (NE, NE)
	50%	NE (29.3, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	91.6% (80.9%, 96.4%)	88.8% (77.9%, 94.5%)
	Month 12	88.4% (75.1%, 94.8%)	86.7% (75.1%, 93.2%)
	Month 18	84.2% (67.7%, 92.7%)	86.7% (75.1%, 93.2%)
	Month 24	84.2% (67.7%, 92.7%)	86.7% (75.1%, 93.2%)
	Month 30	74.8% (47.8%, 89.2%)	86.7% (75.1%, 93.2%)
	Month 36	74.8% (47.8%, 89.2%)	86.7% (75.1%, 93.2%)
	Hazard ratio[b] (95% CI)	0.96 (0.359, 2.547)	
	p-value of 2-sided stratified log-rank test	0.9283	
	p-value from Interaction Test[c]	0.9547	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	12 (13.5%)	3 (3.4%)
	Censored	77 (86.5%)	84 (96.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (33.6, NE)	NE (NE, NE)
	50%	NE (33.6, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	87.6% (78.7%, 92.9%)	96.4% (89.3%, 98.8%)
	Month 12	87.6% (78.7%, 92.9%)	96.4% (89.3%, 98.8%)
	Month 18	87.6% (78.7%, 92.9%)	96.4% (89.3%, 98.8%)
	Month 24	87.6% (78.7%, 92.9%)	96.4% (89.3%, 98.8%)
	Month 30	87.6% (78.7%, 92.9%)	96.4% (89.3%, 98.8%)
	Month 36	76.6% (47.5%, 90.9%)	96.4% (89.3%, 98.8%)
	Hazard ratio[b] (95% CI)	3.86 (1.082, 13.767)	
	p-value of 2-sided stratified log-rank test	0.0253	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	5 (14.3%)	1 (3.3%)
	Censored	30 (85.7%)	29 (96.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (2.3, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	85.3% (68.2%, 93.6%)	96.7% (78.6%, 99.5%)
	Month 12	85.3% (68.2%, 93.6%)	96.7% (78.6%, 99.5%)
	Month 18	85.3% (68.2%, 93.6%)	96.7% (78.6%, 99.5%)
	Month 24	85.3% (68.2%, 93.6%)	96.7% (78.6%, 99.5%)
	Month 30	85.3% (68.2%, 93.6%)	96.7% (78.6%, 99.5%)
	Month 36	85.3% (68.2%, 93.6%)	96.7% (78.6%, 99.5%)
	Hazard ratio[b] (95% CI)	4.21 (0.492, 36.036)	
	p-value of 2-sided stratified log-rank test	0.1533	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	10 (15.4%)	3 (4.7%)
	Censored	55 (84.6%)	61 (95.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (1.8, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	84.4% (73.0%, 91.3%)	95.1% (85.5%, 98.4%)
	Month 12	84.4% (73.0%, 91.3%)	95.1% (85.5%, 98.4%)
	Month 18	84.4% (73.0%, 91.3%)	95.1% (85.5%, 98.4%)
	Month 24	84.4% (73.0%, 91.3%)	95.1% (85.5%, 98.4%)
	Month 30	84.4% (73.0%, 91.3%)	95.1% (85.5%, 98.4%)
	Month 36	84.4% (73.0%, 91.3%)	95.1% (85.5%, 98.4%)
	Hazard ratio[b] (95% CI)	3.61 (0.995, 13.137)	
	p-value of 2-sided stratified log-rank test	0.0374	
	p-value from Interaction Test[c]	0.9843	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	14 (15.7%)	2 (2.3%)
	Censored	75 (84.3%)	85 (97.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (7.9, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	86.2% (76.3%, 92.1%)	97.5% (90.5%, 99.4%)
	Month 12	79.5% (66.9%, 87.7%)	97.5% (90.5%, 99.4%)
	Month 18	79.5% (66.9%, 87.7%)	97.5% (90.5%, 99.4%)
	Month 24	79.5% (66.9%, 87.7%)	97.5% (90.5%, 99.4%)
	Month 30	79.5% (66.9%, 87.7%)	97.5% (90.5%, 99.4%)
	Month 36	79.5% (66.9%, 87.7%)	97.5% (90.5%, 99.4%)
	Hazard ratio[b] (95% CI)	6.79 (1.541, 29.882)	
	p-value of 2-sided stratified log-rank test	0.0033	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	3 (8.6%)	0
	Censored	32 (91.4%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	9 (13.8%)	3 (4.7%)
	Censored	56 (86.2%)	61 (95.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	21.4 (8.4, NE)	NE (NE, NE)
	50%	NE (21.4, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	92.6% (81.4%, 97.2%)	96.5% (86.6%, 99.1%)
	Month 12	84.0% (68.6%, 92.3%)	92.5% (76.3%, 97.8%)
	Month 18	79.8% (62.2%, 89.9%)	92.5% (76.3%, 97.8%)
	Month 24	71.0% (45.4%, 86.2%)	92.5% (76.3%, 97.8%)
	Month 30	71.0% (45.4%, 86.2%)	92.5% (76.3%, 97.8%)
	Month 36	71.0% (45.4%, 86.2%)	92.5% (76.3%, 97.8%)
	Hazard ratio[b] (95% CI)	3.00 (0.811, 11.075)	
	p-value of 2-sided stratified log-rank test	0.0838	
	p-value from Interaction Test[c]	0.7136	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	5 (5.6%)	1 (1.1%)
	Censored	84 (94.4%)	86 (98.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	94.7% (86.5%, 98.0%)	98.8% (91.9%, 99.8%)
	Month 12	92.5% (82.3%, 96.9%)	98.8% (91.9%, 99.8%)
	Month 18	92.5% (82.3%, 96.9%)	98.8% (91.9%, 99.8%)
	Month 24	92.5% (82.3%, 96.9%)	98.8% (91.9%, 99.8%)
	Month 30	92.5% (82.3%, 96.9%)	98.8% (91.9%, 99.8%)
	Month 36	92.5% (82.3%, 96.9%)	98.8% (91.9%, 99.8%)
	Hazard ratio[b] (95% CI)	4.93 (0.575, 42.188)	
	p-value of 2-sided stratified log-rank test	0.1064	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	1 (2.9%)	1 (3.3%)
	Censored	34 (97.1%)	29 (96.7%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	3 (4.6%)	1 (1.6%)
	Censored	62 (95.4%)	63 (98.4%)
	p-value from Interaction Test[c]	0.6554	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	3 (3.4%)	0
	Censored	86 (96.6%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	1 (2.9%)	0
	Censored	34 (97.1%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	1 (1.5%)	0
	Censored	64 (98.5%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	1 (1.1%)	1 (1.1%)
	Censored	88 (98.9%)	86 (98.9%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	2 (5.7%)	0
	Censored	33 (94.3%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	2 (3.1%)	0
	Censored	63 (96.9%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	1 (1.1%)	0
	Censored	88 (98.9%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
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Table 3.5202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade <=2 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_5202_ttirae_le2_dstat.sas, Output: t_3_5202_ttirae_le2_dstat.rtf, Generated on: 11SEP2024 17:40,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	11 (11.5%)	5 (6.1%)
	Censored	85 (88.5%)	77 (93.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	90.2% (82.0%, 94.8%)	96.2% (88.8%, 98.8%)
	Month 12	86.3% (76.0%, 92.4%)	94.4% (85.7%, 97.9%)
	Month 18	86.3% (76.0%, 92.4%)	91.4% (79.2%, 96.6%)
	Month 24	86.3% (76.0%, 92.4%)	91.4% (79.2%, 96.6%)
	Month 30	86.3% (76.0%, 92.4%)	91.4% (79.2%, 96.6%)
	Month 36	86.3% (76.0%, 92.4%)	91.4% (79.2%, 96.6%)
	Hazard ratio[b] (95% CI)	1.96 (0.679, 5.636)	
	p-value of 2-sided stratified log-rank test	0.2051	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	19 (20.4%)	10 (10.1%)
	Censored	74 (79.6%)	89 (89.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	16.7 (6.8, NE)	NE (NE, NE)
	50%	NE (34.5, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	84.4% (75.1%, 90.5%)	90.4% (82.4%, 94.9%)
	Month 12	81.3% (71.1%, 88.2%)	89.0% (80.4%, 94.0%)
	Month 18	74.8% (60.9%, 84.4%)	89.0% (80.4%, 94.0%)
	Month 24	74.8% (60.9%, 84.4%)	89.0% (80.4%, 94.0%)
	Month 30	74.8% (60.9%, 84.4%)	89.0% (80.4%, 94.0%)
	Month 36	65.4% (41.9%, 81.3%)	89.0% (80.4%, 94.0%)
	Hazard ratio[b] (95% CI)	2.20 (0.988, 4.893)	
	p-value of 2-sided stratified log-rank test	0.0478	
	p-value from Interaction Test[c]	0.9870	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	10 (10.4%)	2 (2.4%)
	Censored	86 (89.6%)	80 (97.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	91.2% (83.1%, 95.5%)	100% (100%, 100%)
	Month 12	87.2% (76.9%, 93.1%)	98.1% (87.6%, 99.7%)
	Month 18	87.2% (76.9%, 93.1%)	95.0% (80.5%, 98.8%)
	Month 24	87.2% (76.9%, 93.1%)	95.0% (80.5%, 98.8%)
	Month 30	87.2% (76.9%, 93.1%)	95.0% (80.5%, 98.8%)
	Month 36	87.2% (76.9%, 93.1%)	95.0% (80.5%, 98.8%)
	Hazard ratio[b] (95% CI)	4.54 (0.994, 20.729)	
	p-value of 2-sided stratified log-rank test	0.0321	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	15 (16.1%)	8 (8.1%)
	Censored	78 (83.9%)	91 (91.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	34.5 (15.4, NE)	NE (NE, NE)
	50%	NE (34.5, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	88.8% (80.1%, 93.8%)	92.4% (84.8%, 96.3%)
	Month 12	85.6% (75.8%, 91.7%)	91.0% (82.7%, 95.4%)
	Month 18	78.7% (64.3%, 87.9%)	91.0% (82.7%, 95.4%)
	Month 24	78.7% (64.3%, 87.9%)	91.0% (82.7%, 95.4%)
	Month 30	78.7% (64.3%, 87.9%)	91.0% (82.7%, 95.4%)
	Month 36	68.9% (43.4%, 84.7%)	91.0% (82.7%, 95.4%)
	Hazard ratio[b] (95% CI)	2.13 (0.861, 5.276)	
	p-value of 2-sided stratified log-rank test	0.0939	
	p-value from Interaction Test[c]	0.3308	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects
irAE Category: Immune-mediated Skin Adverse Reactions

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	4 (4.2%)	0
	Censored	92 (95.8%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	8 (8.6%)	3 (3.0%)
	Censored	85 (91.4%)	96 (97.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (34.5, NE)	NE (NE, NE)
	50%	NE (34.5, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects
irAE Category: Immune-mediated Skin Adverse Reactions

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	92.5% (84.9%, 96.3%)	96.9% (90.8%, 99.0%)
	Month 12	92.5% (84.9%, 96.3%)	96.9% (90.8%, 99.0%)
	Month 18	92.5% (84.9%, 96.3%)	96.9% (90.8%, 99.0%)
	Month 24	92.5% (84.9%, 96.3%)	96.9% (90.8%, 99.0%)
	Month 30	92.5% (84.9%, 96.3%)	96.9% (90.8%, 99.0%)
	Month 36	80.9% (47.2%, 94.2%)	96.9% (90.8%, 99.0%)
	Hazard ratio[b] (95% CI)	2.73 (0.715, 10.445)	
	p-value of 2-sided stratified log-rank test	0.1260	
	p-value from Interaction Test[c]	0.9936	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	1 (1.0%)	3 (3.7%)
	Censored	95 (99.0%)	79 (96.3%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	4 (4.3%)	2 (2.0%)
	Censored	89 (95.7%)	97 (98.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	95.5% (88.6%, 98.3%)	98.0% (92.2%, 99.5%)
	Month 12	95.5% (88.6%, 98.3%)	98.0% (92.2%, 99.5%)
	Month 18	95.5% (88.6%, 98.3%)	98.0% (92.2%, 99.5%)
	Month 24	95.5% (88.6%, 98.3%)	98.0% (92.2%, 99.5%)
	Month 30	95.5% (88.6%, 98.3%)	98.0% (92.2%, 99.5%)
	Month 36	95.5% (88.6%, 98.3%)	98.0% (92.2%, 99.5%)
	Hazard ratio[b] (95% CI)	2.30 (0.420, 12.556)	
	p-value of 2-sided stratified log-rank test	0.3227	
	p-value from Interaction Test[c]	0.1462	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	2 (2.1%)	0
	Censored	94 (97.9%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	3 (3.2%)	3 (3.0%)
	Censored	90 (96.8%)	96 (97.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	98.9% (92.2%, 99.8%)	96.5% (89.4%, 98.9%)
	Month 12	97.4% (89.8%, 99.3%)	96.5% (89.4%, 98.9%)
	Month 18	93.8% (79.2%, 98.2%)	96.5% (89.4%, 98.9%)
	Month 24	93.8% (79.2%, 98.2%)	96.5% (89.4%, 98.9%)
	Month 30	93.8% (79.2%, 98.2%)	96.5% (89.4%, 98.9%)
	Month 36	93.8% (79.2%, 98.2%)	96.5% (89.4%, 98.9%)
	Hazard ratio[b] (95% CI)	1.50 (0.248, 9.073)	
	p-value of 2-sided stratified log-rank test	0.6558	
	p-value from Interaction Test[c]	0.9944	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	2 (2.1%)	0
	Censored	94 (97.9%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	1 (1.1%)	2 (2.0%)
	Censored	92 (98.9%)	97 (98.0%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	1 (1.2%)
	Censored	96 (100%)	81 (98.8%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	1 (1.1%)	1 (1.0%)
	Censored	92 (98.9%)	98 (99.0%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	2 (2.1%)	1 (1.2%)
	Censored	94 (97.9%)	81 (98.8%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	1 (1.0%)	0
	Censored	95 (99.0%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	1 (1.0%)	0
	Censored	95 (99.0%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	1 (1.1%)	0
	Censored	92 (98.9%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	1 (1.1%)	0
	Censored	92 (98.9%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	1 (1.1%)	0
	Censored	92 (98.9%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5402_ttirae_ge3_age.sas, Output: t_3_5402_ttirae_ge3_age.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	24 (18.0%)	11 (8.1%)
	Censored	109 (82.0%)	125 (91.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	34.5 (10.3, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	85.9% (78.6%, 90.9%)	92.9% (86.7%, 96.2%)
	Month 12	82.4% (74.0%, 88.3%)	91.8% (85.2%, 95.5%)
	Month 18	78.0% (67.4%, 85.5%)	89.4% (80.3%, 94.4%)
	Month 24	78.0% (67.4%, 85.5%)	89.4% (80.3%, 94.4%)
	Month 30	78.0% (67.4%, 85.5%)	89.4% (80.3%, 94.4%)
	Month 36	72.4% (56.4%, 83.4%)	89.4% (80.3%, 94.4%)
	Hazard ratio[b] (95% CI)	2.43 (1.161, 5.095)	
	p-value of 2-sided stratified log-rank test	0.0150	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	6 (10.7%)	4 (8.9%)
	Censored	50 (89.3%)	41 (91.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (7.6, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	90.8% (79.3%, 96.1%)	93.3% (80.7%, 97.8%)
	Month 12	87.6% (73.7%, 94.4%)	90.1% (75.4%, 96.2%)
	Month 18	87.6% (73.7%, 94.4%)	90.1% (75.4%, 96.2%)
	Month 24	87.6% (73.7%, 94.4%)	90.1% (75.4%, 96.2%)
	Month 30	87.6% (73.7%, 94.4%)	90.1% (75.4%, 96.2%)
	Month 36	87.6% (73.7%, 94.4%)	90.1% (75.4%, 96.2%)
	Hazard ratio[b] (95% CI)	1.19 (0.334, 4.241)	
	p-value of 2-sided stratified log-rank test	0.7889	
	p-value from Interaction Test[c]	0.6199	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	20 (15.0%)	8 (5.9%)
	Censored	113 (85.0%)	128 (94.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	34.5 (15.4, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	88.9% (82.0%, 93.3%)	95.1% (89.3%, 97.8%)
	Month 12	85.3% (77.2%, 90.7%)	94.0% (87.7%, 97.1%)
	Month 18	80.8% (70.0%, 88.0%)	91.5% (82.2%, 96.0%)
	Month 24	80.8% (70.0%, 88.0%)	91.5% (82.2%, 96.0%)
	Month 30	80.8% (70.0%, 88.0%)	91.5% (82.2%, 96.0%)
	Month 36	75.0% (58.2%, 85.8%)	91.5% (82.2%, 96.0%)
	Hazard ratio[b] (95% CI)	2.83 (1.195, 6.709)	
	p-value of 2-sided stratified log-rank test	0.0134	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	5 (8.9%)	2 (4.4%)
	Censored	51 (91.1%)	43 (95.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	92.6% (81.5%, 97.2%)	97.8% (85.3%, 99.7%)
	Month 12	89.3% (75.4%, 95.6%)	94.4% (78.8%, 98.6%)
	Month 18	89.3% (75.4%, 95.6%)	94.4% (78.8%, 98.6%)
	Month 24	89.3% (75.4%, 95.6%)	94.4% (78.8%, 98.6%)
	Month 30	89.3% (75.4%, 95.6%)	94.4% (78.8%, 98.6%)
	Month 36	89.3% (75.4%, 95.6%)	94.4% (78.8%, 98.6%)
	Hazard ratio[b] (95% CI)	1.87 (0.361, 9.738)	
	p-value of 2-sided stratified log-rank test	0.4480	
	p-value from Interaction Test[c]	0.9087	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects
irAE Category: Immune-mediated Skin Adverse Reactions

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	10 (7.5%)	3 (2.2%)
	Censored	123 (92.5%)	133 (97.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (34.5, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects
irAE Category: Immune-mediated Skin Adverse Reactions

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	94.0% (88.3%, 96.9%)	97.7% (93.2%, 99.3%)
	Month 12	92.5% (85.7%, 96.1%)	97.7% (93.2%, 99.3%)
	Month 18	92.5% (85.7%, 96.1%)	97.7% (93.2%, 99.3%)
	Month 24	92.5% (85.7%, 96.1%)	97.7% (93.2%, 99.3%)
	Month 30	92.5% (85.7%, 96.1%)	97.7% (93.2%, 99.3%)
	Month 36	86.3% (67.4%, 94.7%)	97.7% (93.2%, 99.3%)
	Hazard ratio[b] (95% CI)	3.38 (0.929, 12.318)	
	p-value of 2-sided stratified log-rank test	0.0494	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects
irAE Category: Immune-mediated Skin Adverse Reactions

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	2 (3.6%)	0
	Censored	54 (96.4%)	45 (100%)
	p-value from Interaction Test[c]	0.9926	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	4 (3.0%)	3 (2.2%)
	Censored	129 (97.0%)	133 (97.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	97.0% (92.1%, 98.8%)	97.8% (93.3%, 99.3%)
	Month 12	97.0% (92.1%, 98.8%)	97.8% (93.3%, 99.3%)
	Month 18	97.0% (92.1%, 98.8%)	97.8% (93.3%, 99.3%)
	Month 24	97.0% (92.1%, 98.8%)	97.8% (93.3%, 99.3%)
	Month 30	97.0% (92.1%, 98.8%)	97.8% (93.3%, 99.3%)
	Month 36	97.0% (92.1%, 98.8%)	97.8% (93.3%, 99.3%)
	Hazard ratio[b] (95% CI)	1.43 (0.319, 6.407)	
	p-value of 2-sided stratified log-rank test	0.6375	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	1 (1.8%)	2 (4.4%)
	Censored	55 (98.2%)	43 (95.6%)
	p-value from Interaction Test[c]	0.4189	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	3 (2.3%)	2 (1.5%)
	Censored	130 (97.7%)	134 (98.5%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	99.2% (94.6%, 99.9%)	98.0% (92.3%, 99.5%)
	Month 12	98.2% (92.8%, 99.5%)	98.0% (92.3%, 99.5%)
	Month 18	95.7% (85.5%, 98.8%)	98.0% (92.3%, 99.5%)
	Month 24	95.7% (85.5%, 98.8%)	98.0% (92.3%, 99.5%)
	Month 30	95.7% (85.5%, 98.8%)	98.0% (92.3%, 99.5%)
	Month 36	95.7% (85.5%, 98.8%)	98.0% (92.3%, 99.5%)
	Hazard ratio[b] (95% CI)	2.63 (0.273, 25.306)	
	p-value of 2-sided stratified log-rank test	0.3853	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	2 (3.6%)	1 (2.2%)
	Censored	54 (96.4%)	44 (97.8%)
	p-value from Interaction Test[c]	0.6179	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	2 (1.5%)	2 (1.5%)
	Censored	131 (98.5%)	134 (98.5%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	1 (1.8%)	0
	Censored	55 (98.2%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	1 (0.8%)	1 (0.7%)
	Censored	132 (99.2%)	135 (99.3%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	1 (2.2%)
	Censored	56 (100%)	44 (97.8%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	1 (0.8%)	1 (0.7%)
	Censored	132 (99.2%)	135 (99.3%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	1 (1.8%)	0
	Censored	55 (98.2%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	0	0
	Censored	133 (100%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	1 (1.8%)	0
	Censored	55 (98.2%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	1 (0.8%)	0
	Censored	132 (99.2%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
Data Cutoff Date: 22SEP2023

Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	1 (0.8%)	0
	Censored	132 (99.2%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	1 (0.8%)	0
	Censored	132 (99.2%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	1 (0.8%)	0
	Censored	132 (99.2%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Region
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5502_ttirae_ge3_reg.sas, Output: t_3_5502_ttirae_ge3_reg.rtf, Generated on: 06SEP2024 01:23,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	9 (10.1%)	8 (9.2%)
	Censored	80 (89.9%)	79 (90.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (14.1, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	90.7% (82.3%, 95.3%)	94.2% (86.5%, 97.5%)
	Month 12	89.0% (79.7%, 94.2%)	90.7% (81.2%, 95.5%)
	Month 18	89.0% (79.7%, 94.2%)	85.7% (69.2%, 93.7%)
	Month 24	89.0% (79.7%, 94.2%)	85.7% (69.2%, 93.7%)
	Month 30	89.0% (79.7%, 94.2%)	85.7% (69.2%, 93.7%)
	Month 36	89.0% (79.7%, 94.2%)	85.7% (69.2%, 93.7%)
	Hazard ratio[b] (95% CI)	1.05 (0.404, 2.724)	
	p-value of 2-sided stratified log-rank test	0.9206	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	6 (17.1%)	1 (3.3%)
	Censored	29 (82.9%)	29 (96.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	34.5 (3.3, NE)	NE (5.8, NE)
	50%	NE (34.5, NE)	NE (NE, NE)
	75%	NE (34.5, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	88.5% (72.1%, 95.5%)	95.7% (72.9%, 99.4%)
	Month 12	84.5% (66.2%, 93.3%)	95.7% (72.9%, 99.4%)
	Month 18	84.5% (66.2%, 93.3%)	95.7% (72.9%, 99.4%)
	Month 24	84.5% (66.2%, 93.3%)	95.7% (72.9%, 99.4%)
	Month 30	84.5% (66.2%, 93.3%)	95.7% (72.9%, 99.4%)
	Month 36	63.3% (19.3%, 88.1%)	95.7% (72.9%, 99.4%)
	Hazard ratio[b] (95% CI)	>999.99 (0.000, NE)	
	p-value of 2-sided stratified log-rank test	0.0230	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	15 (23.1%)	6 (9.4%)
	Censored	50 (76.9%)	58 (90.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	15.4 (3.5, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	82.0% (69.7%, 89.6%)	90.2% (79.5%, 95.5%)
	Month 12	76.9% (62.9%, 86.2%)	90.2% (79.5%, 95.5%)
	Month 18	69.0% (51.9%, 81.1%)	90.2% (79.5%, 95.5%)
	Month 24	69.0% (51.9%, 81.1%)	90.2% (79.5%, 95.5%)
	Month 30	69.0% (51.9%, 81.1%)	90.2% (79.5%, 95.5%)
	Month 36	69.0% (51.9%, 81.1%)	90.2% (79.5%, 95.5%)
	Hazard ratio[b] (95% CI)	2.60 (1.008, 6.703)	
	p-value of 2-sided stratified log-rank test	0.0400	
	p-value from Interaction Test[c]	0.2347	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	5 (5.6%)	5 (5.7%)
	Censored	84 (94.4%)	82 (94.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (14.1, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	95.2% (87.7%, 98.2%)	97.6% (90.9%, 99.4%)
	Month 12	93.4% (84.6%, 97.3%)	94.1% (84.7%, 97.8%)
	Month 18	93.4% (84.6%, 97.3%)	88.9% (70.6%, 96.1%)
	Month 24	93.4% (84.6%, 97.3%)	88.9% (70.6%, 96.1%)
	Month 30	93.4% (84.6%, 97.3%)	88.9% (70.6%, 96.1%)
	Month 36	93.4% (84.6%, 97.3%)	88.9% (70.6%, 96.1%)
	Hazard ratio[b] (95% CI)	0.91 (0.264, 3.157)	
	p-value of 2-sided stratified log-rank test	0.8850	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	6 (17.1%)	1 (3.3%)
	Censored	29 (82.9%)	29 (96.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	34.5 (3.3, NE)	NE (5.8, NE)
	50%	NE (34.5, NE)	NE (NE, NE)
	75%	NE (34.5, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	88.5% (72.1%, 95.5%)	95.7% (72.9%, 99.4%)
	Month 12	84.5% (66.2%, 93.3%)	95.7% (72.9%, 99.4%)
	Month 18	84.5% (66.2%, 93.3%)	95.7% (72.9%, 99.4%)
	Month 24	84.5% (66.2%, 93.3%)	95.7% (72.9%, 99.4%)
	Month 30	84.5% (66.2%, 93.3%)	95.7% (72.9%, 99.4%)
	Month 36	63.3% (19.3%, 88.1%)	95.7% (72.9%, 99.4%)
	Hazard ratio[b] (95% CI)	>999.99 (0.000, NE)	
	p-value of 2-sided stratified log-rank test	0.0230	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	14 (21.5%)	4 (6.3%)
	Censored	51 (78.5%)	60 (93.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	15.4 (3.9, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	83.5% (71.4%, 90.8%)	93.4% (83.2%, 97.5%)
	Month 12	78.4% (64.5%, 87.4%)	93.4% (83.2%, 97.5%)
	Month 18	70.4% (53.0%, 82.3%)	93.4% (83.2%, 97.5%)
	Month 24	70.4% (53.0%, 82.3%)	93.4% (83.2%, 97.5%)
	Month 30	70.4% (53.0%, 82.3%)	93.4% (83.2%, 97.5%)
	Month 36	70.4% (53.0%, 82.3%)	93.4% (83.2%, 97.5%)
	Hazard ratio[b] (95% CI)	3.67 (1.206, 11.142)	
	p-value of 2-sided stratified log-rank test	0.0141	
	p-value from Interaction Test[c]	0.1880	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	1 (1.1%)	1 (1.1%)
	Censored	88 (98.9%)	86 (98.9%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	4 (11.4%)	0
	Censored	31 (88.6%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	7 (10.8%)	2 (3.1%)
	Censored	58 (89.2%)	62 (96.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (10.3, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	90.8% (80.6%, 95.7%)	96.8% (87.9%, 99.2%)
	Month 12	87.5% (74.6%, 94.1%)	96.8% (87.9%, 99.2%)
	Month 18	87.5% (74.6%, 94.1%)	96.8% (87.9%, 99.2%)
	Month 24	87.5% (74.6%, 94.1%)	96.8% (87.9%, 99.2%)
	Month 30	87.5% (74.6%, 94.1%)	96.8% (87.9%, 99.2%)
	Month 36	87.5% (74.6%, 94.1%)	96.8% (87.9%, 99.2%)
	Hazard ratio[b] (95% CI)	3.60 (0.749, 17.355)	
	p-value of 2-sided stratified log-rank test	0.0869	
	p-value from Interaction Test[c]	0.7458	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	4 (4.5%)	3 (3.4%)
	Censored	85 (95.5%)	84 (96.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	95.5% (88.4%, 98.3%)	96.5% (89.5%, 98.9%)
	Month 12	95.5% (88.4%, 98.3%)	96.5% (89.5%, 98.9%)
	Month 18	95.5% (88.4%, 98.3%)	96.5% (89.5%, 98.9%)
	Month 24	95.5% (88.4%, 98.3%)	96.5% (89.5%, 98.9%)
	Month 30	95.5% (88.4%, 98.3%)	96.5% (89.5%, 98.9%)
	Month 36	95.5% (88.4%, 98.3%)	96.5% (89.5%, 98.9%)
	Hazard ratio[b] (95% CI)	1.28 (0.286, 5.708)	
	p-value of 2-sided stratified log-rank test	0.7483	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	1 (1.5%)	2 (3.1%)
	Censored	64 (98.5%)	62 (96.9%)
	p-value from Interaction Test[c]	0.7912	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	2 (2.2%)	0
	Censored	87 (97.8%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	1 (3.3%)
	Censored	35 (100%)	29 (96.7%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	3 (4.6%)	2 (3.1%)
	Censored	62 (95.4%)	62 (96.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (16.7, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	98.3% (88.4%, 99.8%)	96.5% (86.5%, 99.1%)
	Month 12	96.0% (84.9%, 99.0%)	96.5% (86.5%, 99.1%)
	Month 18	91.2% (72.4%, 97.4%)	96.5% (86.5%, 99.1%)
	Month 24	91.2% (72.4%, 97.4%)	96.5% (86.5%, 99.1%)
	Month 30	91.2% (72.4%, 97.4%)	96.5% (86.5%, 99.1%)
	Month 36	91.2% (72.4%, 97.4%)	96.5% (86.5%, 99.1%)
	Hazard ratio[b] (95% CI)	1.45 (0.242, 8.697)	
	p-value of 2-sided stratified log-rank test	0.6817	
	p-value from Interaction Test[c]	>.9999	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	2 (2.2%)	2 (2.3%)
	Censored	87 (97.8%)	85 (97.7%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	1 (1.5%)	0
	Censored	64 (98.5%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	2 (2.3%)
	Censored	89 (100%)	85 (97.7%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	1 (2.9%)	0
	Censored	34 (97.1%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	1 (1.1%)	1 (1.1%)
	Censored	88 (98.9%)	86 (98.9%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	1 (1.5%)	0
	Censored	64 (98.5%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	1 (1.1%)	0
	Censored	88 (98.9%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	1 (1.5%)	0
	Censored	64 (98.5%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	1 (1.5%)	0
	Censored	64 (98.5%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	1 (2.9%)	0
	Censored	34 (97.1%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	1 (1.1%)	0
	Censored	88 (98.9%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
Data Cutoff Date: 22SEP2023

Table 3.5602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Adverse Events of Grade >=3 by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_5602_ttirae_ge3_dstat.sas, Output: t_3_5602_ttirae_ge3_dstat.rtf, Generated on: 06SEP2024 01:21,
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	5 (5.2%)	0
	Censored	91 (94.8%)	82 (100%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	95.6% (88.8%, 98.3%)	100% (100%, 100%)
	Month 12	93.9% (85.5%, 97.5%)	100% (100%, 100%)
	Month 18	93.9% (85.5%, 97.5%)	100% (100%, 100%)
	Month 24	93.9% (85.5%, 97.5%)	100% (100%, 100%)
	Month 30	93.9% (85.5%, 97.5%)	100% (100%, 100%)
	Month 36	93.9% (85.5%, 97.5%)	100% (100%, 100%)
	Hazard ratio[b] (95% CI)	- (-,-)	
	p-value of 2-sided stratified log-rank test	0.0365	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	7 (7.5%)	4 (4.0%)
	Censored	86 (92.5%)	95 (96.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (34.5, NE)	NE (NE, NE)
	50%	NE (34.5, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	93.3% (85.6%, 96.9%)	96.7% (90.1%, 98.9%)
	Month 12	93.3% (85.6%, 96.9%)	95.2% (87.6%, 98.2%)
	Month 18	93.3% (85.6%, 96.9%)	95.2% (87.6%, 98.2%)
	Month 24	93.3% (85.6%, 96.9%)	95.2% (87.6%, 98.2%)
	Month 30	93.3% (85.6%, 96.9%)	95.2% (87.6%, 98.2%)
	Month 36	81.6% (46.8%, 94.7%)	95.2% (87.6%, 98.2%)
	Hazard ratio[b] (95% CI)	2.28 (0.580, 8.969)	
	p-value of 2-sided stratified log-rank test	0.2255	
	p-value from Interaction Test[c]	0.9927	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	4 (4.2%)	0
	Censored	92 (95.8%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	4 (4.3%)	4 (4.0%)
	Censored	89 (95.7%)	95 (96.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (34.5, NE)	NE (NE, NE)
	50%	NE (34.5, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	96.6% (89.7%, 98.9%)	96.7% (90.1%, 98.9%)
	Month 12	96.6% (89.7%, 98.9%)	95.2% (87.6%, 98.2%)
	Month 18	96.6% (89.7%, 98.9%)	95.2% (87.6%, 98.2%)
	Month 24	96.6% (89.7%, 98.9%)	95.2% (87.6%, 98.2%)
	Month 30	96.6% (89.7%, 98.9%)	95.2% (87.6%, 98.2%)
	Month 36	84.5% (44.4%, 96.6%)	95.2% (87.6%, 98.2%)
	Hazard ratio[b] (95% CI)	1.18 (0.257, 5.451)	
	p-value of 2-sided stratified log-rank test	0.8279	
	p-value from Interaction Test[c]	0.9932	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	1 (1.0%)	0
	Censored	95 (99.0%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	3 (3.2%)	0
	Censored	90 (96.8%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	2 (2.1%)	0
	Censored	94 (97.9%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	2 (2.0%)
	Censored	93 (100%)	97 (98.0%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	2 (2.2%)	0
	Censored	91 (97.8%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	2 (2.0%)
	Censored	93 (100%)	97 (98.0%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	2 (2.2%)	0
	Censored	91 (97.8%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	1 (1.0%)	0
	Censored	95 (99.0%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	1 (1.0%)	0
	Censored	95 (99.0%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
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Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	0
	Censored	96 (100%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.5802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	0	0
	Censored	93 (100%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_5802_ttirae_ser_age.sas, Output: t_3_5802_ttirae_ser_age.rtf, Generated on: 06SEP2024 00:47,
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	8 (6.0%)	3 (2.2%)
	Censored	125 (94.0%)	133 (97.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (34.5, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5902_ttirae_ser_reg.sas, Output: t_3_5902_ttirae_ser_reg.rtf, Generated on: 06SEP2024 00:48,
Data Cutoff Date: 22SEP2023

Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	94.5% (88.8%, 97.3%)	98.3% (93.2%, 99.6%)
	Month 12	94.5% (88.8%, 97.3%)	97.2% (91.3%, 99.1%)
	Month 18	94.5% (88.8%, 97.3%)	97.2% (91.3%, 99.1%)
	Month 24	94.5% (88.8%, 97.3%)	97.2% (91.3%, 99.1%)
	Month 30	94.5% (88.8%, 97.3%)	97.2% (91.3%, 99.1%)
	Month 36	87.8% (66.0%, 96.0%)	97.2% (91.3%, 99.1%)
	Hazard ratio[b] (95% CI)	3.79 (0.802, 17.871)	
	p-value of 2-sided stratified log-rank test	0.0707	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5902_ttirae_ser_reg.sas, Output: t_3_5902_ttirae_ser_reg.rtf, Generated on: 06SEP2024 00:48,
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	4 (7.1%)	1 (2.2%)
	Censored	52 (92.9%)	44 (97.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5902_ttirae_ser_reg.sas, Output: t_3_5902_ttirae_ser_reg.rtf, Generated on: 06SEP2024 00:48,
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	94.4% (83.7%, 98.2%)	97.8% (85.3%, 99.7%)
	Month 12	91.1% (77.0%, 96.7%)	97.8% (85.3%, 99.7%)
	Month 18	91.1% (77.0%, 96.7%)	97.8% (85.3%, 99.7%)
	Month 24	91.1% (77.0%, 96.7%)	97.8% (85.3%, 99.7%)
	Month 30	91.1% (77.0%, 96.7%)	97.8% (85.3%, 99.7%)
	Month 36	91.1% (77.0%, 96.7%)	97.8% (85.3%, 99.7%)
	Hazard ratio[b] (95% CI)	3.15 (0.349, 28.379)	
	p-value of 2-sided stratified log-rank test	0.2813	
	p-value from Interaction Test[c]	0.6331	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5902_ttirae_ser_reg.sas, Output: t_3_5902_ttirae_ser_reg.rtf, Generated on: 06SEP2024 00:48,
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	6 (4.5%)	3 (2.2%)
	Censored	127 (95.5%)	133 (97.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (34.5, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5902_ttirae_ser_reg.sas, Output: t_3_5902_ttirae_ser_reg.rtf, Generated on: 06SEP2024 00:48,
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	96.0% (90.7%, 98.3%)	98.3% (93.2%, 99.6%)
	Month 12	96.0% (90.7%, 98.3%)	97.2% (91.3%, 99.1%)
	Month 18	96.0% (90.7%, 98.3%)	97.2% (91.3%, 99.1%)
	Month 24	96.0% (90.7%, 98.3%)	97.2% (91.3%, 99.1%)
	Month 30	96.0% (90.7%, 98.3%)	97.2% (91.3%, 99.1%)
	Month 36	89.2% (65.5%, 96.9%)	97.2% (91.3%, 99.1%)
	Hazard ratio[b] (95% CI)	2.75 (0.554, 13.667)	
	p-value of 2-sided stratified log-rank test	0.1964	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5902_ttirae_ser_reg.sas, Output: t_3_5902_ttirae_ser_reg.rtf, Generated on: 06SEP2024 00:48,
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	2 (3.6%)	1 (2.2%)
	Censored	54 (96.4%)	44 (97.8%)
	p-value from Interaction Test[c]	0.8629	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5902_ttirae_ser_reg.sas, Output: t_3_5902_ttirae_ser_reg.rtf, Generated on: 06SEP2024 00:48,
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	2 (1.5%)	0
	Censored	131 (98.5%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5902_ttirae_ser_reg.sas, Output: t_3_5902_ttirae_ser_reg.rtf, Generated on: 06SEP2024 00:48,
Data Cutoff Date: 22SEP2023

Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	2 (3.6%)	0
	Censored	54 (96.4%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	1 (0.8%)	2 (1.5%)
	Censored	132 (99.2%)	134 (98.5%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	1 (1.8%)	0
	Censored	55 (98.2%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	2 (1.5%)	0
	Censored	131 (98.5%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	0	1 (0.7%)
	Censored	133 (100%)	135 (99.3%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	1 (2.2%)
	Censored	56 (100%)	44 (97.8%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	2 (1.5%)	0
	Censored	131 (98.5%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	0	0
	Censored	133 (100%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	1 (1.8%)	0
	Censored	55 (98.2%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	1 (0.8%)	0
	Censored	132 (99.2%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5902_ttirae_ser_reg.sas, Output: t_3_5902_ttirae_ser_reg.rtf, Generated on: 06SEP2024 00:48,
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5902_ttirae_ser_reg.sas, Output: t_3_5902_ttirae_ser_reg.rtf, Generated on: 06SEP2024 00:48,
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	0	0
	Censored	133 (100%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	0	0
	Censored	133 (100%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5902_ttirae_ser_reg.sas, Output: t_3_5902_ttirae_ser_reg.rtf, Generated on: 06SEP2024 00:48,
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	0	0
	Censored	133 (100%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
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Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	0	0
	Censored	133 (100%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5902_ttirae_ser_reg.sas, Output: t_3_5902_ttirae_ser_reg.rtf, Generated on: 06SEP2024 00:48,
Data Cutoff Date: 22SEP2023

Table 3.5902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Region (Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	0
	Censored	56 (100%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_5902_ttirae_ser_reg.sas, Output: t_3_5902_ttirae_ser_reg.rtf, Generated on: 06SEP2024 00:48,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	5 (5.6%)	2 (2.3%)
	Censored	84 (94.4%)	85 (97.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	95.4% (88.3%, 98.3%)	98.8% (91.9%, 99.8%)
	Month 12	93.6% (85.0%, 97.3%)	97.1% (88.7%, 99.3%)
	Month 18	93.6% (85.0%, 97.3%)	97.1% (88.7%, 99.3%)
	Month 24	93.6% (85.0%, 97.3%)	97.1% (88.7%, 99.3%)
	Month 30	93.6% (85.0%, 97.3%)	97.1% (88.7%, 99.3%)
	Month 36	93.6% (85.0%, 97.3%)	97.1% (88.7%, 99.3%)
	Hazard ratio[b] (95% CI)	2.42 (0.470, 12.505)	
	p-value of 2-sided stratified log-rank test	0.2745	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	4 (11.4%)	1 (3.3%)
	Censored	31 (88.6%)	29 (96.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	34.5 (3.3, NE)	NE (5.8, NE)
	50%	NE (34.5, NE)	NE (NE, NE)
	75%	NE (34.5, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	91.1% (74.8%, 97.0%)	95.7% (72.9%, 99.4%)
	Month 12	91.1% (74.8%, 97.0%)	95.7% (72.9%, 99.4%)
	Month 18	91.1% (74.8%, 97.0%)	95.7% (72.9%, 99.4%)
	Month 24	91.1% (74.8%, 97.0%)	95.7% (72.9%, 99.4%)
	Month 30	91.1% (74.8%, 97.0%)	95.7% (72.9%, 99.4%)
	Month 36	68.3% (17.8%, 91.9%)	95.7% (72.9%, 99.4%)
	Hazard ratio[b] (95% CI)	>999.99 (0.000, NE)	
	p-value of 2-sided stratified log-rank test	0.0622	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: All irAEs

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	3 (4.6%)	1 (1.6%)
	Censored	62 (95.4%)	63 (98.4%)
	p-value from Interaction Test[c]	0.9370	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	2 (2.2%)	2 (2.3%)
	Censored	87 (97.8%)	85 (97.7%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	4 (11.4%)	1 (3.3%)
	Censored	31 (88.6%)	29 (96.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	34.5 (3.3, NE)	NE (5.8, NE)
	50%	NE (34.5, NE)	NE (NE, NE)
	75%	NE (34.5, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	91.1% (74.8%, 97.0%)	95.7% (72.9%, 99.4%)
	Month 12	91.1% (74.8%, 97.0%)	95.7% (72.9%, 99.4%)
	Month 18	91.1% (74.8%, 97.0%)	95.7% (72.9%, 99.4%)
	Month 24	91.1% (74.8%, 97.0%)	95.7% (72.9%, 99.4%)
	Month 30	91.1% (74.8%, 97.0%)	95.7% (72.9%, 99.4%)
	Month 36	68.3% (17.8%, 91.9%)	95.7% (72.9%, 99.4%)
	Hazard ratio[b] (95% CI)	>999.99 (0.000, NE)	
	p-value of 2-sided stratified log-rank test	0.0622	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Non-hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	2 (3.1%)	1 (1.6%)
	Censored	63 (96.9%)	63 (98.4%)
	p-value from Interaction Test[c]	0.6421	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	3 (3.4%)	0
	Censored	86 (96.6%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Hypersensitivity

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	1 (1.5%)	0
	Censored	64 (98.5%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	1 (1.1%)	2 (2.3%)
	Censored	88 (98.9%)	85 (97.7%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Endocrinopathies

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	1 (1.5%)	0
	Censored	64 (98.5%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	2 (5.7%)	0
	Censored	33 (94.3%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Gastrointestinal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	1 (3.3%)
	Censored	35 (100%)	29 (96.7%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Hepatic

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	1 (1.6%)
	Censored	65 (100%)	63 (98.4%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects
irAE Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	2 (5.7%)	0
	Censored	33 (94.3%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Skin Adverse Reactions

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	1 (1.1%)	0
	Censored	88 (98.9%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Cardiovascular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Nervous System

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	1 (1.5%)	0
	Censored	64 (98.5%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Musculoskeletal

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
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Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Ocular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pancreatitis

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	0	0
	Censored	89 (100%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Immune-Related Serious Adverse Events by irAE Category by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

irAE Category: Immune-mediated Pulmonary

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	0	0
	Censored	65 (100%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Immune-related Adverse Events are identified as any >=Grade 2 AEs based on a pre-specified preferred terms (PTs) list.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6002_ttirae_ser_dstat.sas, Output: t_3_6002_ttirae_ser_dstat.rtf, Generated on: 06SEP2024 00:47,
Data Cutoff Date: 22SEP2023

Table 3.6202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	20 (20.8%)	19 (23.2%)
	Censored	76 (79.2%)	63 (76.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (0.8, NE)	NE (0.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_6202_ttirr_age.sas, Output: t_3_6202_ttirr_age.rtf, Generated on: 20SEP2024 17:26,
Data Cutoff Date: 22SEP2023

Table 3.6202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	79.0% (69.4%, 85.9%)	76.5% (65.6%, 84.3%)
	Month 12	79.0% (69.4%, 85.9%)	76.5% (65.6%, 84.3%)
	Month 18	79.0% (69.4%, 85.9%)	76.5% (65.6%, 84.3%)
	Month 24	79.0% (69.4%, 85.9%)	76.5% (65.6%, 84.3%)
	Month 30	79.0% (69.4%, 85.9%)	76.5% (65.6%, 84.3%)
	Month 36	79.0% (69.4%, 85.9%)	76.5% (65.6%, 84.3%)
	Hazard ratio[b] (95% CI)	0.87 (0.463, 1.629)	
	p-value of 2-sided stratified log-rank test	0.6664	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_6202_ttirr_age.sas, Output: t_3_6202_ttirr_age.rtf, Generated on: 20SEP2024 17:26,
Data Cutoff Date: 22SEP2023

Table 3.6202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	12 (12.9%)	17 (17.2%)
	Censored	81 (87.1%)	82 (82.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (1.4, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_6202_ttirr_age.sas, Output: t_3_6202_ttirr_age.rtf, Generated on: 20SEP2024 17:26,
Data Cutoff Date: 22SEP2023

Table 3.6202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	86.8% (78.0%, 92.3%)	82.7% (73.7%, 88.9%)
	Month 12	86.8% (78.0%, 92.3%)	82.7% (73.7%, 88.9%)
	Month 18	86.8% (78.0%, 92.3%)	82.7% (73.7%, 88.9%)
	Month 24	86.8% (78.0%, 92.3%)	82.7% (73.7%, 88.9%)
	Month 30	86.8% (78.0%, 92.3%)	82.7% (73.7%, 88.9%)
	Month 36	86.8% (78.0%, 92.3%)	82.7% (73.7%, 88.9%)
	Hazard ratio[b] (95% CI)	0.71 (0.340, 1.500)	
	p-value of 2-sided stratified log-rank test	0.3728	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_6202_ttirr_age.sas, Output: t_3_6202_ttirr_age.rtf, Generated on: 20SEP2024 17:26,
Data Cutoff Date: 22SEP2023

Table 3.6202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	p-value from Interaction Test[c]	0.7054	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_6202_ttirr_age.sas, Output: t_3_6202_ttirr_age.rtf, Generated on: 20SEP2024 17:26,
Data Cutoff Date: 22SEP2023

Table 3.6302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	25 (18.8%)	29 (21.3%)
	Censored	108 (81.2%)	107 (78.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (2.1, NE)	NE (0.8, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_6302_ttirr_reg.sas, Output: t_3_6302_ttirr_reg.rtf, Generated on: 20SEP2024 17:28,
Data Cutoff Date: 22SEP2023

Table 3.6302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	81.0% (73.2%, 86.7%)	78.4% (70.4%, 84.5%)
	Month 12	81.0% (73.2%, 86.7%)	78.4% (70.4%, 84.5%)
	Month 18	81.0% (73.2%, 86.7%)	78.4% (70.4%, 84.5%)
	Month 24	81.0% (73.2%, 86.7%)	78.4% (70.4%, 84.5%)
	Month 30	81.0% (73.2%, 86.7%)	78.4% (70.4%, 84.5%)
	Month 36	81.0% (73.2%, 86.7%)	78.4% (70.4%, 84.5%)
	Hazard ratio[b] (95% CI)	0.84 (0.492, 1.441)	
	p-value of 2-sided stratified log-rank test	0.5295	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_6302_ttirr_reg.sas, Output: t_3_6302_ttirr_reg.rtf, Generated on: 20SEP2024 17:28,
Data Cutoff Date: 22SEP2023

Table 3.6302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	7 (12.5%)	7 (15.6%)
	Censored	49 (87.5%)	38 (84.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (2.6, NE)	NE (0.8, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_6302_ttirr_reg.sas, Output: t_3_6302_ttirr_reg.rtf, Generated on: 20SEP2024 17:28,
Data Cutoff Date: 22SEP2023

Table 3.6302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	87.2% (74.9%, 93.7%)	84.4% (70.1%, 92.3%)
	Month 12	87.2% (74.9%, 93.7%)	84.4% (70.1%, 92.3%)
	Month 18	87.2% (74.9%, 93.7%)	84.4% (70.1%, 92.3%)
	Month 24	87.2% (74.9%, 93.7%)	84.4% (70.1%, 92.3%)
	Month 30	87.2% (74.9%, 93.7%)	84.4% (70.1%, 92.3%)
	Month 36	87.2% (74.9%, 93.7%)	84.4% (70.1%, 92.3%)
	Hazard ratio[b] (95% CI)	0.80 (0.280, 2.300)	
	p-value of 2-sided stratified log-rank test	0.6852	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_6302_ttirr_reg.sas, Output: t_3_6302_ttirr_reg.rtf, Generated on: 20SEP2024 17:28,
Data Cutoff Date: 22SEP2023

Table 3.6302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	p-value from Interaction Test[c]	0.9298	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_6302_ttirr_reg.sas, Output: t_3_6302_ttirr_reg.rtf, Generated on: 20SEP2024 17:28,
Data Cutoff Date: 22SEP2023

Table 3.6402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	16 (18.0%)	18 (20.7%)
	Censored	73 (82.0%)	69 (79.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (2.6, NE)	NE (0.8, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6402_ttirr_dis.sas, Output: t_3_6402_ttirr_dis.rtf, Generated on: 20SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.6402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	81.8% (72.1%, 88.5%)	79.1% (68.9%, 86.3%)
	Month 12	81.8% (72.1%, 88.5%)	79.1% (68.9%, 86.3%)
	Month 18	81.8% (72.1%, 88.5%)	79.1% (68.9%, 86.3%)
	Month 24	81.8% (72.1%, 88.5%)	79.1% (68.9%, 86.3%)
	Month 30	81.8% (72.1%, 88.5%)	79.1% (68.9%, 86.3%)
	Month 36	81.8% (72.1%, 88.5%)	79.1% (68.9%, 86.3%)
	Hazard ratio[b] (95% CI)	0.82 (0.420, 1.617)	
	p-value of 2-sided stratified log-rank test	0.5806	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6402_ttirr_dis.sas, Output: t_3_6402_ttirr_dis.rtf, Generated on: 20SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.6402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	6 (17.1%)	7 (23.3%)
	Censored	29 (82.9%)	23 (76.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (0.0, NE)	NE (0.0, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6402_ttirr_dis.sas, Output: t_3_6402_ttirr_dis.rtf, Generated on: 20SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.6402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	82.9% (65.8%, 91.9%)	76.5% (57.0%, 88.1%)
	Month 12	82.9% (65.8%, 91.9%)	76.5% (57.0%, 88.1%)
	Month 18	82.9% (65.8%, 91.9%)	76.5% (57.0%, 88.1%)
	Month 24	82.9% (65.8%, 91.9%)	76.5% (57.0%, 88.1%)
	Month 30	82.9% (65.8%, 91.9%)	76.5% (57.0%, 88.1%)
	Month 36	82.9% (65.8%, 91.9%)	76.5% (57.0%, 88.1%)
	Hazard ratio[b] (95% CI)	0.68 (0.229, 2.035)	
	p-value of 2-sided stratified log-rank test	0.4711	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6402_ttirr_dis.sas, Output: t_3_6402_ttirr_dis.rtf, Generated on: 20SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.6402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	10 (15.4%)	11 (17.2%)
	Censored	55 (84.6%)	53 (82.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (1.4, NE)	NE (0.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6402_ttirr_dis.sas, Output: t_3_6402_ttirr_dis.rtf, Generated on: 20SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.6402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	84.1% (72.5%, 91.2%)	82.6% (70.8%, 90.0%)
	Month 12	84.1% (72.5%, 91.2%)	82.6% (70.8%, 90.0%)
	Month 18	84.1% (72.5%, 91.2%)	82.6% (70.8%, 90.0%)
	Month 24	84.1% (72.5%, 91.2%)	82.6% (70.8%, 90.0%)
	Month 30	84.1% (72.5%, 91.2%)	82.6% (70.8%, 90.0%)
	Month 36	84.1% (72.5%, 91.2%)	82.6% (70.8%, 90.0%)
	Hazard ratio[b] (95% CI)	0.89 (0.376, 2.088)	
	p-value of 2-sided stratified log-rank test	0.7907	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6402_ttirr_dis.sas, Output: t_3_6402_ttirr_dis.rtf, Generated on: 20SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.6402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	p-value from Interaction Test[c]	0.9820	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_6402_ttirr_dis.sas, Output: t_3_6402_ttirr_dis.rtf, Generated on: 20SEP2024 17:29,
Data Cutoff Date: 22SEP2023

Table 3.6602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	20 (20.8%)	17 (20.7%)
	Censored	76 (79.2%)	65 (79.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (0.8, NE)	NE (0.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6602_ttirr_le2_age.sas, Output: t_3_6602_ttirr_le2_age.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.6602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	79.0% (69.4%, 85.9%)	79.0% (68.3%, 86.4%)
	Month 12	79.0% (69.4%, 85.9%)	79.0% (68.3%, 86.4%)
	Month 18	79.0% (69.4%, 85.9%)	79.0% (68.3%, 86.4%)
	Month 24	79.0% (69.4%, 85.9%)	79.0% (68.3%, 86.4%)
	Month 30	79.0% (69.4%, 85.9%)	79.0% (68.3%, 86.4%)
	Month 36	79.0% (69.4%, 85.9%)	79.0% (68.3%, 86.4%)
	Hazard ratio[b] (95% CI)	0.97 (0.507, 1.853)	
	p-value of 2-sided stratified log-rank test	0.9378	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6602_ttirr_le2_age.sas, Output: t_3_6602_ttirr_le2_age.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.6602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	9 (9.7%)	16 (16.2%)
	Censored	84 (90.3%)	83 (83.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (2.8, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6602_ttirr_le2_age.sas, Output: t_3_6602_ttirr_le2_age.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.6602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	90.2% (82.0%, 94.8%)	83.8% (74.8%, 89.7%)
	Month 12	90.2% (82.0%, 94.8%)	83.8% (74.8%, 89.7%)
	Month 18	90.2% (82.0%, 94.8%)	83.8% (74.8%, 89.7%)
	Month 24	90.2% (82.0%, 94.8%)	83.8% (74.8%, 89.7%)
	Month 30	90.2% (82.0%, 94.8%)	83.8% (74.8%, 89.7%)
	Month 36	90.2% (82.0%, 94.8%)	83.8% (74.8%, 89.7%)
	Hazard ratio[b] (95% CI)	0.55 (0.244, 1.254)	
	p-value of 2-sided stratified log-rank test	0.1499	
	p-value from Interaction Test[c]	0.3120	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6602_ttirr_le2_age.sas, Output: t_3_6602_ttirr_le2_age.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.6702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	23 (17.3%)	28 (20.6%)
	Censored	110 (82.7%)	108 (79.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (3.7, NE)	NE (0.8, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6702_ttirr_le2_reg.sas, Output: t_3_6702_ttirr_le2_reg.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.6702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	82.5% (74.9%, 88.0%)	79.1% (71.2%, 85.1%)
	Month 12	82.5% (74.9%, 88.0%)	79.1% (71.2%, 85.1%)
	Month 18	82.5% (74.9%, 88.0%)	79.1% (71.2%, 85.1%)
	Month 24	82.5% (74.9%, 88.0%)	79.1% (71.2%, 85.1%)
	Month 30	82.5% (74.9%, 88.0%)	79.1% (71.2%, 85.1%)
	Month 36	82.5% (74.9%, 88.0%)	79.1% (71.2%, 85.1%)
	Hazard ratio[b] (95% CI)	0.78 (0.450, 1.364)	
	p-value of 2-sided stratified log-rank test	0.3887	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6702_ttirr_le2_reg.sas, Output: t_3_6702_ttirr_le2_reg.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.6702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	6 (10.7%)	5 (11.1%)
	Censored	50 (89.3%)	40 (88.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6702_ttirr_le2_reg.sas, Output: t_3_6702_ttirr_le2_reg.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.6702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	89.1% (77.2%, 94.9%)	88.9% (75.3%, 95.2%)
	Month 12	89.1% (77.2%, 94.9%)	88.9% (75.3%, 95.2%)
	Month 18	89.1% (77.2%, 94.9%)	88.9% (75.3%, 95.2%)
	Month 24	89.1% (77.2%, 94.9%)	88.9% (75.3%, 95.2%)
	Month 30	89.1% (77.2%, 94.9%)	88.9% (75.3%, 95.2%)
	Month 36	89.1% (77.2%, 94.9%)	88.9% (75.3%, 95.2%)
	Hazard ratio[b] (95% CI)	0.93 (0.282, 3.073)	
	p-value of 2-sided stratified log-rank test	0.9071	
	p-value from Interaction Test[c]	0.7785	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6702_ttirr_le2_reg.sas, Output: t_3_6702_ttirr_le2_reg.rtf, Generated on: 03SEP2024 15:54,
Data Cutoff Date: 22SEP2023

Table 3.6802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	14 (15.7%)	16 (18.4%)
	Censored	75 (84.3%)	71 (81.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (3.5, NE)	NE (1.4, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6802_ttirr_le2_dstat.sas, Output: t_3_6802_ttirr_le2_dstat.rtf, Generated on: 03SEP2024 15:55,
Data Cutoff Date: 22SEP2023

Table 3.6802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	84.1% (74.6%, 90.3%)	81.4% (71.5%, 88.2%)
	Month 12	84.1% (74.6%, 90.3%)	81.4% (71.5%, 88.2%)
	Month 18	84.1% (74.6%, 90.3%)	81.4% (71.5%, 88.2%)
	Month 24	84.1% (74.6%, 90.3%)	81.4% (71.5%, 88.2%)
	Month 30	84.1% (74.6%, 90.3%)	81.4% (71.5%, 88.2%)
	Month 36	84.1% (74.6%, 90.3%)	81.4% (71.5%, 88.2%)
	Hazard ratio[b] (95% CI)	0.81 (0.395, 1.663)	
	p-value of 2-sided stratified log-rank test	0.5770	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6802_ttirr_le2_dstat.sas, Output: t_3_6802_ttirr_le2_dstat.rtf, Generated on: 03SEP2024 15:55,
Data Cutoff Date: 22SEP2023

Table 3.6802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	6 (17.1%)	7 (23.3%)
	Censored	29 (82.9%)	23 (76.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (0.0, NE)	NE (0.0, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6802_ttirr_le2_dstat.sas, Output: t_3_6802_ttirr_le2_dstat.rtf, Generated on: 03SEP2024 15:55,
Data Cutoff Date: 22SEP2023

Table 3.6802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	82.9% (65.8%, 91.9%)	76.5% (57.0%, 88.1%)
	Month 12	82.9% (65.8%, 91.9%)	76.5% (57.0%, 88.1%)
	Month 18	82.9% (65.8%, 91.9%)	76.5% (57.0%, 88.1%)
	Month 24	82.9% (65.8%, 91.9%)	76.5% (57.0%, 88.1%)
	Month 30	82.9% (65.8%, 91.9%)	76.5% (57.0%, 88.1%)
	Month 36	82.9% (65.8%, 91.9%)	76.5% (57.0%, 88.1%)
	Hazard ratio[b] (95% CI)	0.68 (0.229, 2.035)	
	p-value of 2-sided stratified log-rank test	0.4711	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6802_ttirr_le2_dstat.sas, Output: t_3_6802_ttirr_le2_dstat.rtf, Generated on: 03SEP2024 15:55,
Data Cutoff Date: 22SEP2023

Table 3.6802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	9 (13.8%)	10 (15.6%)
	Censored	56 (86.2%)	54 (84.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (3.7, NE)	NE (0.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6802_ttirr_le2_dstat.sas, Output: t_3_6802_ttirr_le2_dstat.rtf, Generated on: 03SEP2024 15:55,
Data Cutoff Date: 22SEP2023

Table 3.6802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade <=2 by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	85.7% (74.2%, 92.3%)	84.2% (72.6%, 91.2%)
	Month 12	85.7% (74.2%, 92.3%)	84.2% (72.6%, 91.2%)
	Month 18	85.7% (74.2%, 92.3%)	84.2% (72.6%, 91.2%)
	Month 24	85.7% (74.2%, 92.3%)	84.2% (72.6%, 91.2%)
	Month 30	85.7% (74.2%, 92.3%)	84.2% (72.6%, 91.2%)
	Month 36	85.7% (74.2%, 92.3%)	84.2% (72.6%, 91.2%)
	Hazard ratio[b] (95% CI)	0.87 (0.354, 2.144)	
	p-value of 2-sided stratified log-rank test	0.7706	
	p-value from Interaction Test[c]	0.9845	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_6802_ttirr_le2_dstat.sas, Output: t_3_6802_ttirr_le2_dstat.rtf, Generated on: 03SEP2024 15:55,
Data Cutoff Date: 22SEP2023

Table 3.7002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade >=3 by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	0	2 (2.4%)
	Censored	96 (100%)	80 (97.6%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_7002_ttirr_ge3_age.sas, Output: t_3_7002_ttirr_ge3_age.rtf, Generated on: 05SEP2024 13:29,
Data Cutoff Date: 22SEP2023

Table 3.7002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade >=3 by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	4 (4.3%)	2 (2.0%)
	Censored	89 (95.7%)	97 (98.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_7002_ttirr_ge3_age.sas, Output: t_3_7002_ttirr_ge3_age.rtf, Generated on: 05SEP2024 13:29,
Data Cutoff Date: 22SEP2023

Table 3.7002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade >=3 by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	95.5% (88.6%, 98.3%)	98.0% (92.2%, 99.5%)
	Month 12	95.5% (88.6%, 98.3%)	98.0% (92.2%, 99.5%)
	Month 18	95.5% (88.6%, 98.3%)	98.0% (92.2%, 99.5%)
	Month 24	95.5% (88.6%, 98.3%)	98.0% (92.2%, 99.5%)
	Month 30	95.5% (88.6%, 98.3%)	98.0% (92.2%, 99.5%)
	Month 36	95.5% (88.6%, 98.3%)	98.0% (92.2%, 99.5%)
	Hazard ratio[b] (95% CI)	2.30 (0.420, 12.556)	
	p-value of 2-sided stratified log-rank test	0.3227	
	p-value from Interaction Test[c]	0.9943	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_7002_ttirr_ge3_age.sas, Output: t_3_7002_ttirr_ge3_age.rtf, Generated on: 05SEP2024 13:29,
Data Cutoff Date: 22SEP2023

Table 3.7102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade >=3 by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	3 (2.3%)	2 (1.5%)
	Censored	130 (97.7%)	134 (98.5%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_7102_ttirr_ge3_reg.sas, Output: t_3_7102_ttirr_ge3_reg.rtf, Generated on: 03SEP2024 15:55,
Data Cutoff Date: 22SEP2023

Table 3.7102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade >=3 by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	97.7% (93.1%, 99.3%)	98.5% (94.2%, 99.6%)
	Month 12	97.7% (93.1%, 99.3%)	98.5% (94.2%, 99.6%)
	Month 18	97.7% (93.1%, 99.3%)	98.5% (94.2%, 99.6%)
	Month 24	97.7% (93.1%, 99.3%)	98.5% (94.2%, 99.6%)
	Month 30	97.7% (93.1%, 99.3%)	98.5% (94.2%, 99.6%)
	Month 36	97.7% (93.1%, 99.3%)	98.5% (94.2%, 99.6%)
	Hazard ratio[b] (95% CI)	1.60 (0.267, 9.598)	
	p-value of 2-sided stratified log-rank test	0.6031	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_7102_ttirr_ge3_reg.sas, Output: t_3_7102_ttirr_ge3_reg.rtf, Generated on: 03SEP2024 15:55,
Data Cutoff Date: 22SEP2023

Table 3.7102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade >=3 by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	1 (1.8%)	2 (4.4%)
	Censored	55 (98.2%)	43 (95.6%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_7102_ttirr_ge3_reg.sas, Output: t_3_7102_ttirr_ge3_reg.rtf, Generated on: 03SEP2024 15:55,
Data Cutoff Date: 22SEP2023

Table 3.7202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade >=3 by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	3 (3.4%)	2 (2.3%)
	Censored	86 (96.6%)	85 (97.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_7202_ttirr_ge3_dstat.sas, Output: t_3_7202_ttirr_ge3_dstat.rtf, Generated on: 03SEP2024 15:56,
Data Cutoff Date: 22SEP2023

Table 3.7202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade >=3 by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	96.6% (89.7%, 98.9%)	97.6% (90.9%, 99.4%)
	Month 12	96.6% (89.7%, 98.9%)	97.6% (90.9%, 99.4%)
	Month 18	96.6% (89.7%, 98.9%)	97.6% (90.9%, 99.4%)
	Month 24	96.6% (89.7%, 98.9%)	97.6% (90.9%, 99.4%)
	Month 30	96.6% (89.7%, 98.9%)	97.6% (90.9%, 99.4%)
	Month 36	96.6% (89.7%, 98.9%)	97.6% (90.9%, 99.4%)
	Hazard ratio[b] (95% CI)	1.44 (0.241, 8.622)	
	p-value of 2-sided stratified log-rank test	0.6878	

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_7202_ttirr_ge3_dstat.sas, Output: t_3_7202_ttirr_ge3_dstat.rtf, Generated on: 03SEP2024 15:56,
Data Cutoff Date: 22SEP2023

Table 3.7202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade >=3 by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_7202_ttirr_ge3_dstat.sas, Output: t_3_7202_ttirr_ge3_dstat.rtf, Generated on: 03SEP2024 15:56,
Data Cutoff Date: 22SEP2023

Table 3.7202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Infusion-Related Reactions of Grade >=3 by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	1 (1.5%)	2 (3.1%)
	Censored	64 (98.5%)	62 (96.9%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_7202_ttirr_ge3_dstat.sas, Output: t_3_7202_ttirr_ge3_dstat.rtf, Generated on: 03SEP2024 15:56,
Data Cutoff Date: 22SEP2023

Table 3.113 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Infusion-Related Reactions by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	1 (1.0%)	0
	Censored	95 (99.0%)	82 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_7402_ttirr_ser_age.sas, Output: t_3_7402_ttirr_ser_age.rtf, Generated on: 21AUG2024 13:54,
Data Cutoff Date: 22SEP2023

Table 3.113 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Infusion-Related Reactions by Age Group (Safety Analysis Set): MMRp/MSS Subjects

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	3 (3.2%)	0
	Censored	90 (96.8%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Program: t_3_7402_ttirr_ser_age.sas, Output: t_3_7402_ttirr_ser_age.rtf, Generated on: 21AUG2024 13:54,
Data Cutoff Date: 22SEP2023

Table 3.7502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Infusion-Related Reactions by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	2 (1.5%)	0
	Censored	131 (98.5%)	136 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_7502_ttirr_ser_reg.sas, Output: t_3_7502_ttirr_ser_reg.rtf, Generated on: 21AUG2024 14:00,
Data Cutoff Date: 22SEP2023

Table 3.7502 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Infusion-Related Reactions by Region (Safety Analysis Set): MMRp/MSS Subjects

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	2 (3.6%)	0
	Censored	54 (96.4%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Program: t_3_7502_ttirr_ser_reg.sas, Output: t_3_7502_ttirr_ser_reg.rtf, Generated on: 21AUG2024 14:00,
Data Cutoff Date: 22SEP2023

Table 3.7602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Infusion-Related Reactions by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	3 (3.4%)	0
	Censored	86 (96.6%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_7602_ttirr_ser_dis.sas, Output: t_3_7602_ttirr_ser_dis.rtf, Generated on: 21AUG2024 14:01,
Data Cutoff Date: 22SEP2023

Table 3.7602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Infusion-Related Reactions by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_7602_ttirr_ser_dis.sas, Output: t_3_7602_ttirr_ser_dis.rtf, Generated on: 21AUG2024 14:01,
Data Cutoff Date: 22SEP2023

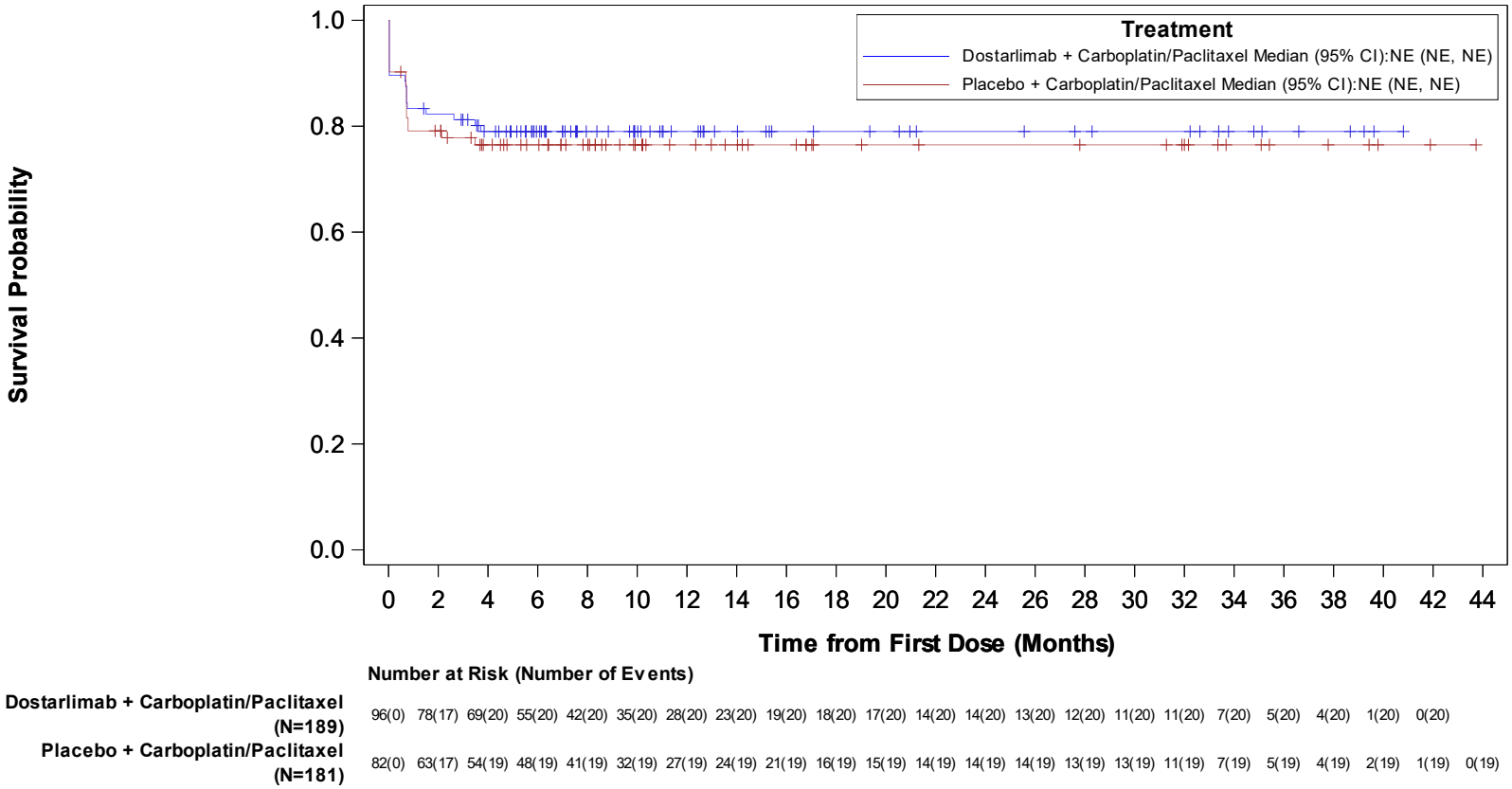
Table 3.7602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Infusion-Related Reactions by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	1 (1.5%)	0
	Censored	64 (98.5%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Program: t_3_7602_ttirr_ser_dis.sas, Output: t_3_7602_ttirr_ser_dis.rtf, Generated on: 21AUG2024 14:01,
Data Cutoff Date: 22SEP2023

Figure 3.6202 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Infusion-Related Reactions by Age Group (Safety Analysis Set): MMRp/MSS Subjects

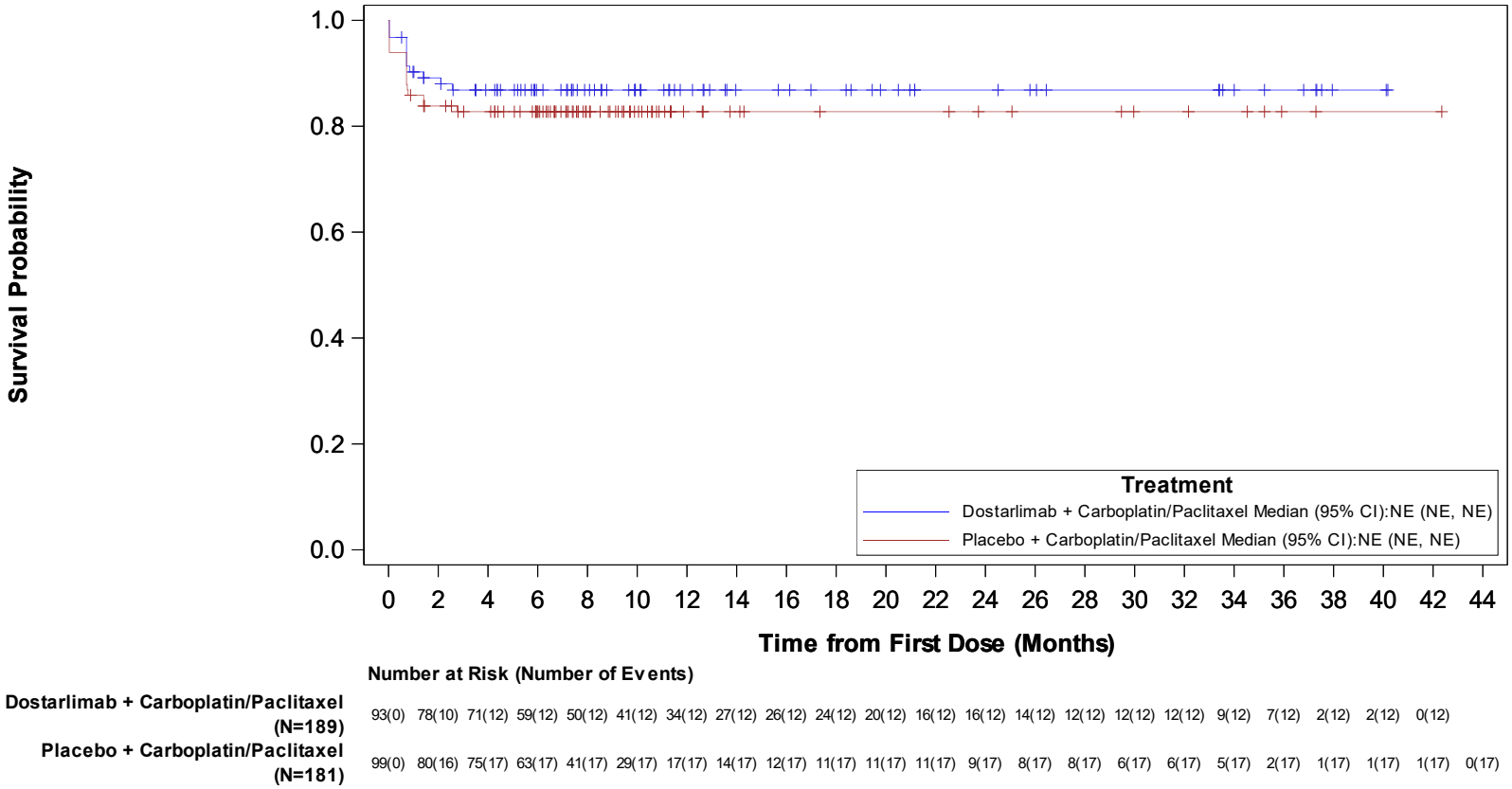
Age Group: <65



NE = Not Estimable.
Program: f_3_6202_km_irr_age.sas, Output: f_3_6202_km_irr_age.rtf, Generated on: 20SEP2024 17:27,
Data Cutoff Date: 22SEP2023

Figure 3.6202 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Infusion-Related Reactions by Age Group (Safety Analysis Set): MMRp/MSS Subjects

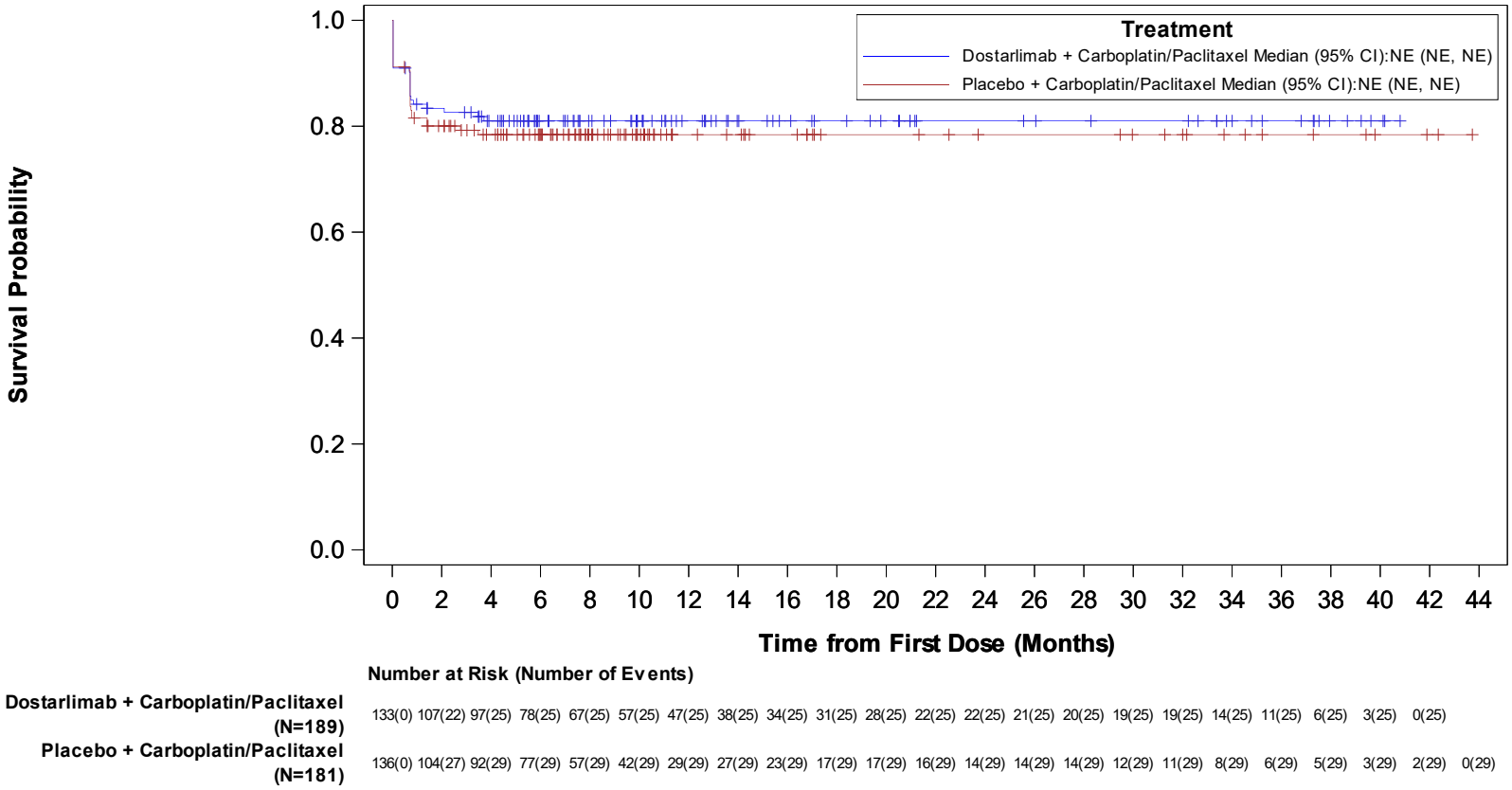
Age Group: >=65



NE = Not Estimable.
Program: f_3_6202_km_irr_age.sas, Output: f_3_6202_km_irr_age.rtf, Generated on: 20SEP2024 17:27,
Data Cutoff Date: 22SEP2023

Figure 3.6302 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Infusion-Related Reactions by Region (Safety Analysis Set): MMRp/MSS Subjects

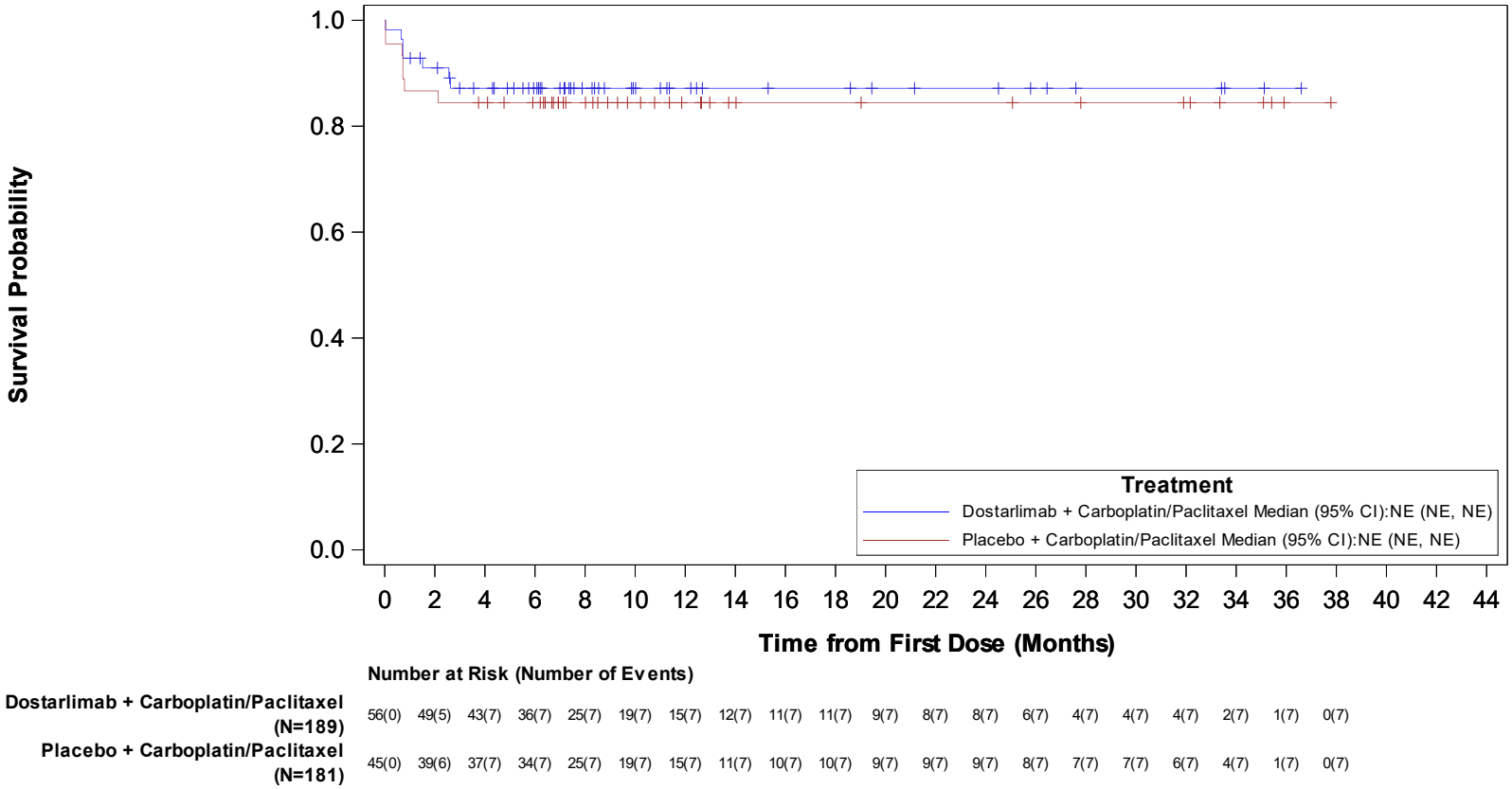
Region: North America



NE = Not Estimable.
Program: f_3_6302_km_irr_reg.sas, Output: f_3_6302_km_irr_reg.rtf, Generated on: 20SEP2024 17:28,
Data Cutoff Date: 22SEP2023

Figure 3.6302 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Infusion-Related Reactions by Region (Safety Analysis Set): MMRp/MSS Subjects

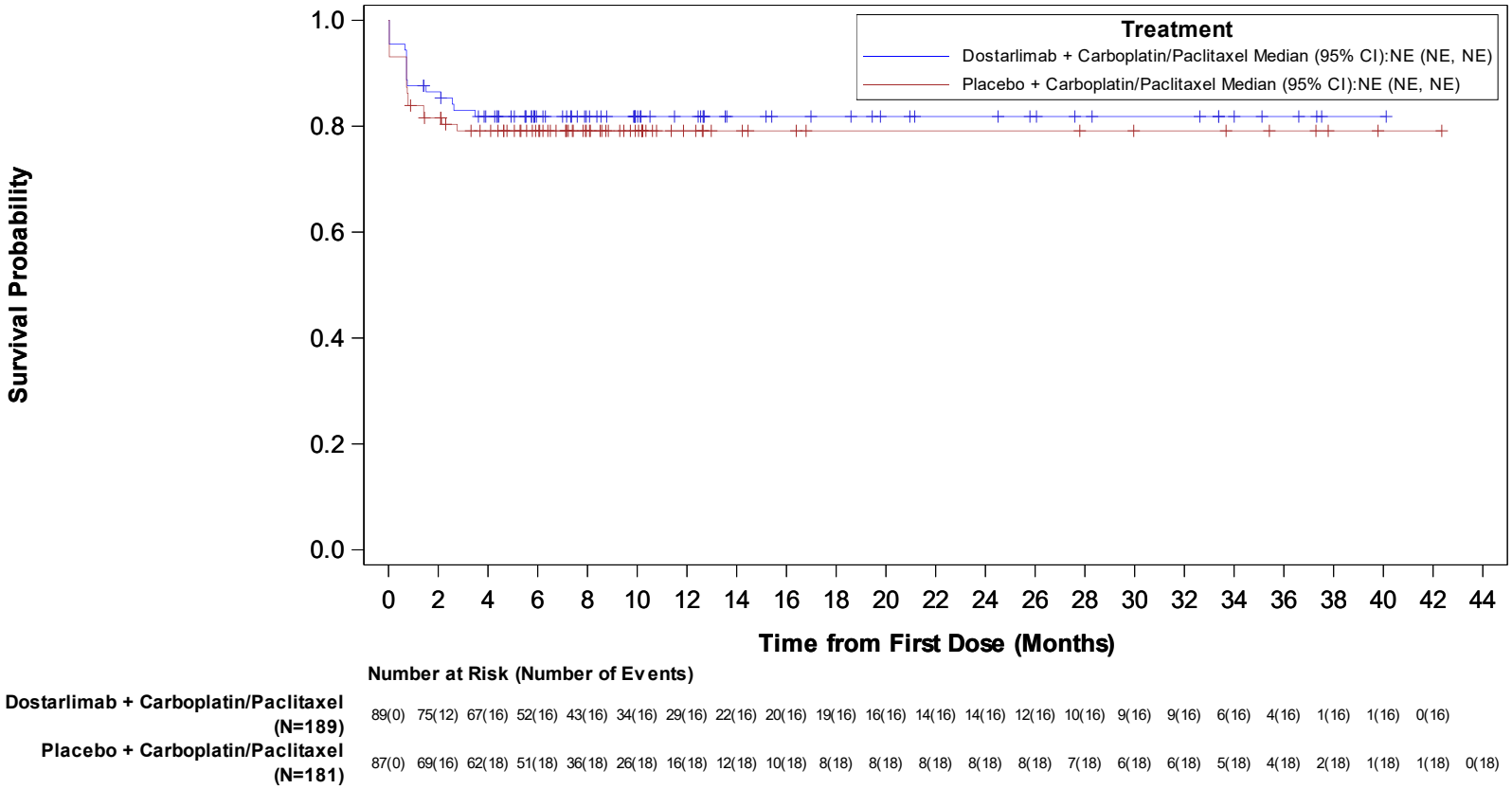
Region: Europe



NE = Not Estimable.
Program: f_3_6302_km_irr_reg.sas, Output: f_3_6302_km_irr_reg.rtf, Generated on: 20SEP2024 17:28,
Data Cutoff Date: 22SEP2023

Figure 3.6402 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Infusion-Related Reactions by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

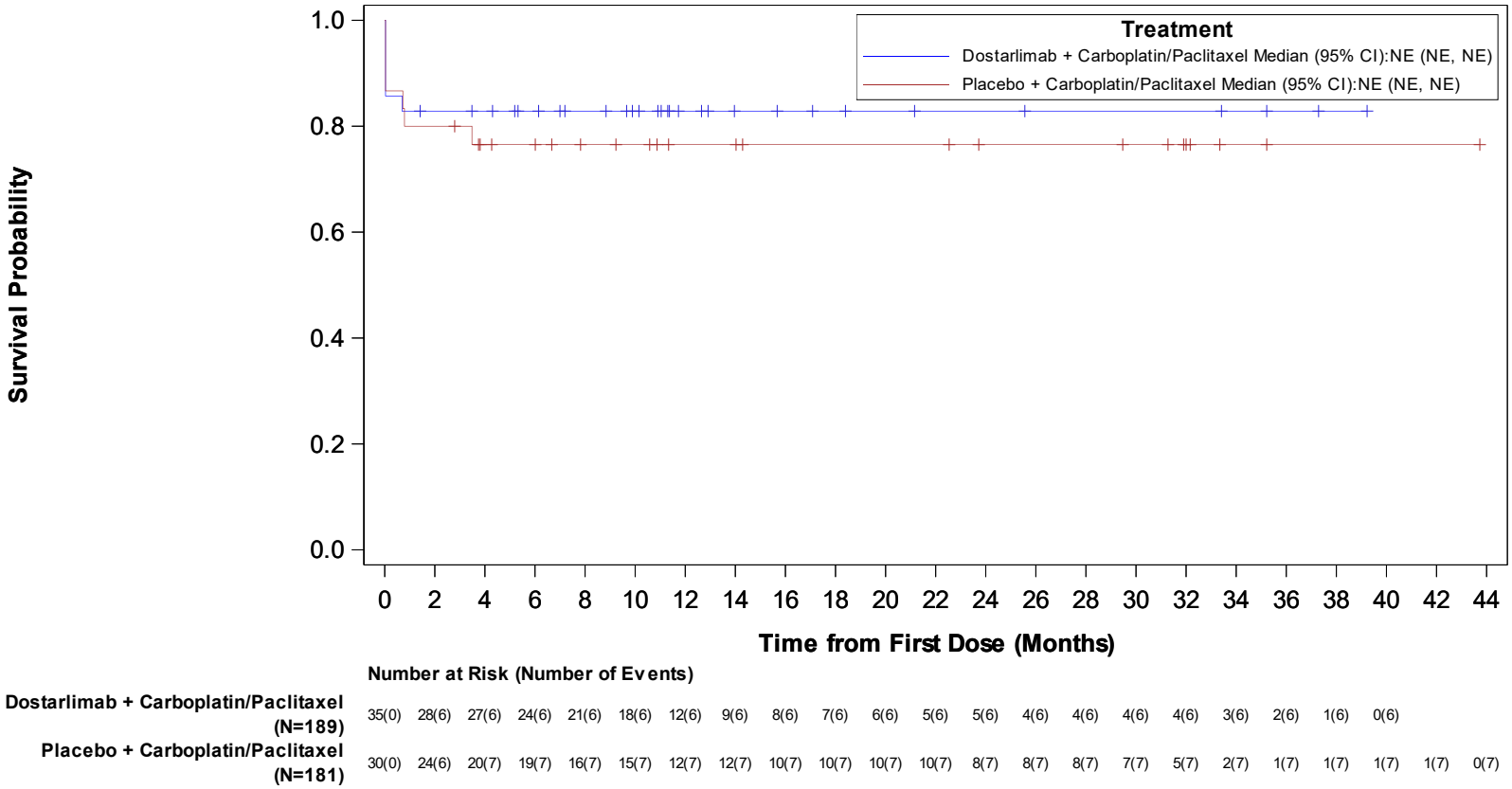
Disease Status: Recurrent



NE = Not Estimable.
Program: f_3_6402_km_irr_dstat.sas, Output: f_3_6402_km_irr_dstat.rtf, Generated on: 20SEP2024 17:30,
Data Cutoff Date: 22SEP2023

Figure 3.6402 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Infusion-Related Reactions by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

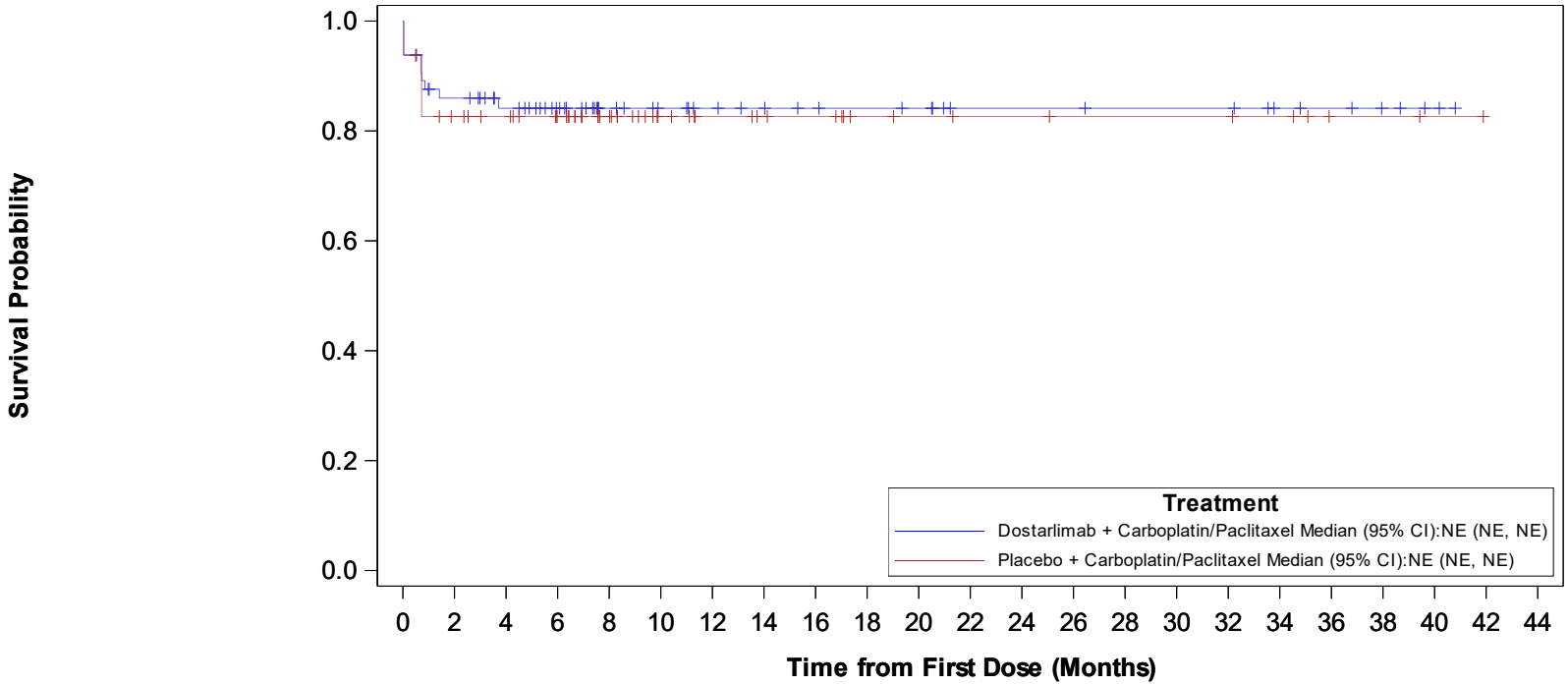
Disease Status: Primary Stage III



NE = Not Estimable.
Program: f_3_6402_km_irr_dstat.sas, Output: f_3_6402_km_irr_dstat.rtf, Generated on: 20SEP2024 17:30,
Data Cutoff Date: 22SEP2023

Figure 3.6402 Graph of Kaplan Meier Curves of Time to Treatment-Emergent Infusion-Related Reactions by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

Disease Status: Primary Stage IV



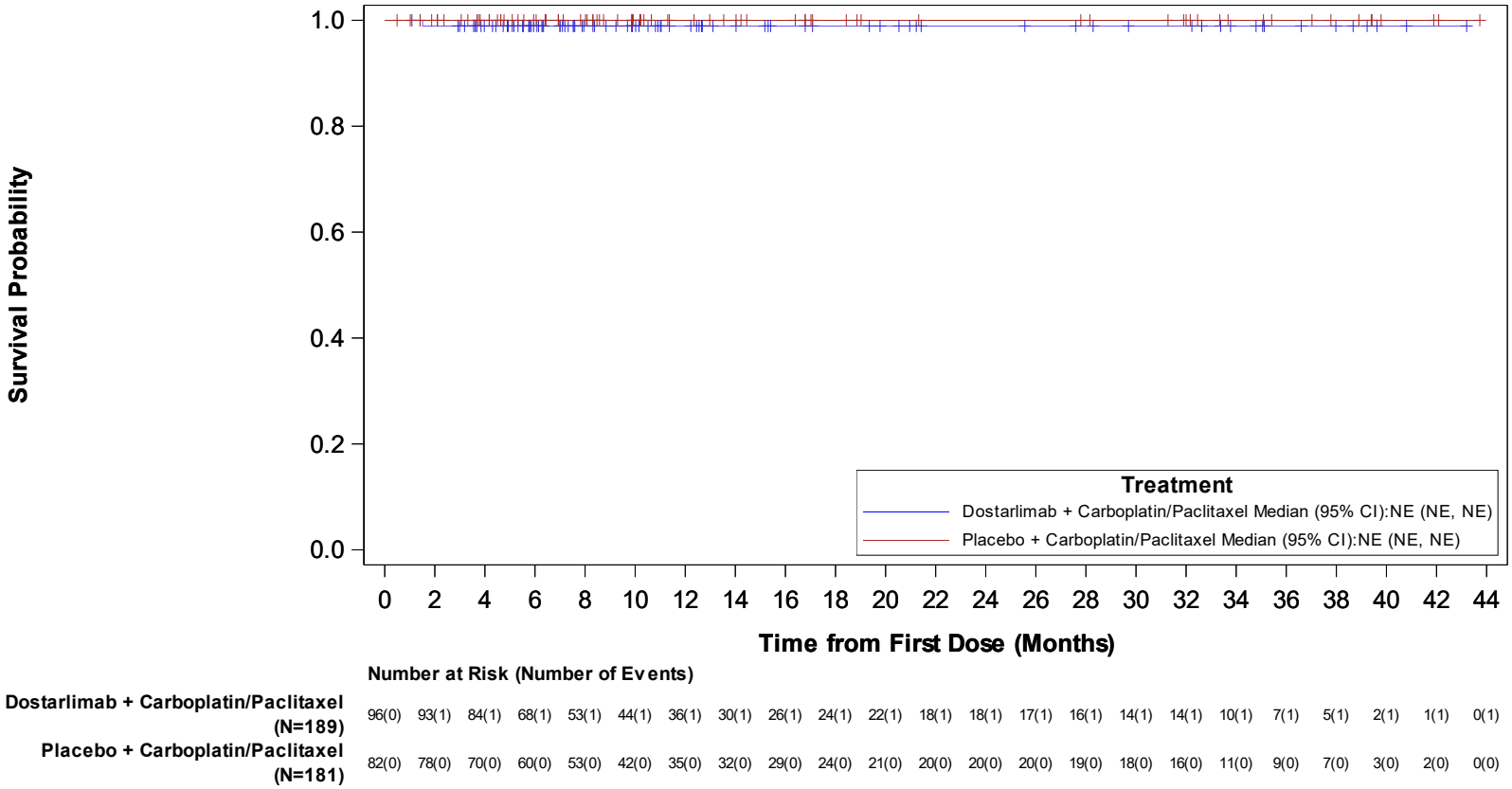
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	65(0)	53(9)	46(10)	38(10)	28(10)	24(10)	21(10)	19(10)	17(10)	16(10)	15(10)	11(10)	11(10)	11(10)	10(10)	10(10)	10(10)	7(10)	6(10)	4(10)	2(10)	0(10)
Placebo + Carboplatin/Paclitaxel (N=181)	64(0)	50(11)	47(11)	41(11)	30(11)	20(11)	16(11)	14(11)	13(11)	9(11)	8(11)	7(11)	7(11)	6(11)	6(11)	6(11)	6(11)	5(11)	2(11)	2(11)	1(11)	0(11)

NE = Not Estimable.
Program: f_3_6402_km_irr_dstat.sas, Output: f_3_6402_km_irr_dstat.rtf, Generated on: 20SEP2024 17:30,
Data Cutoff Date: 22SEP2023

Figure 3.7402 Kaplan Meier Plot of Time to Treatment-Emergent Serious Infusion-related reactions by Age Group (Safety Analysis Set):MMRp/MSS Subjects

Age Group: <65



NE = Not Estimable.
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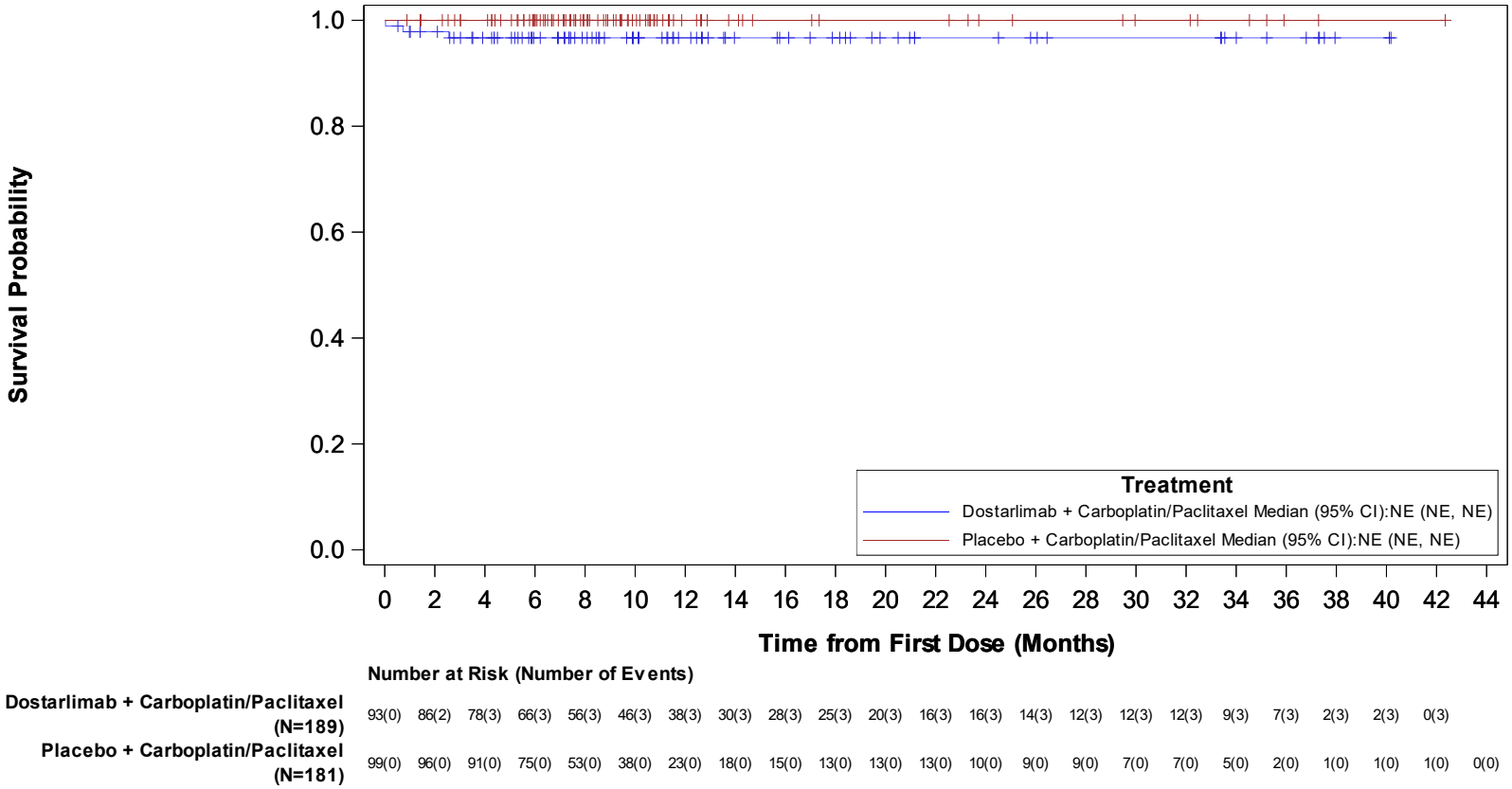
Data Cutoff Date: 22SEP2023

Figure 3.7402 Kaplan Meier Plot of Time to Treatment-Emergent Serious Infusion-related reactions by Age Group (Safety Analysis Set):MMRp/MSS Subjects

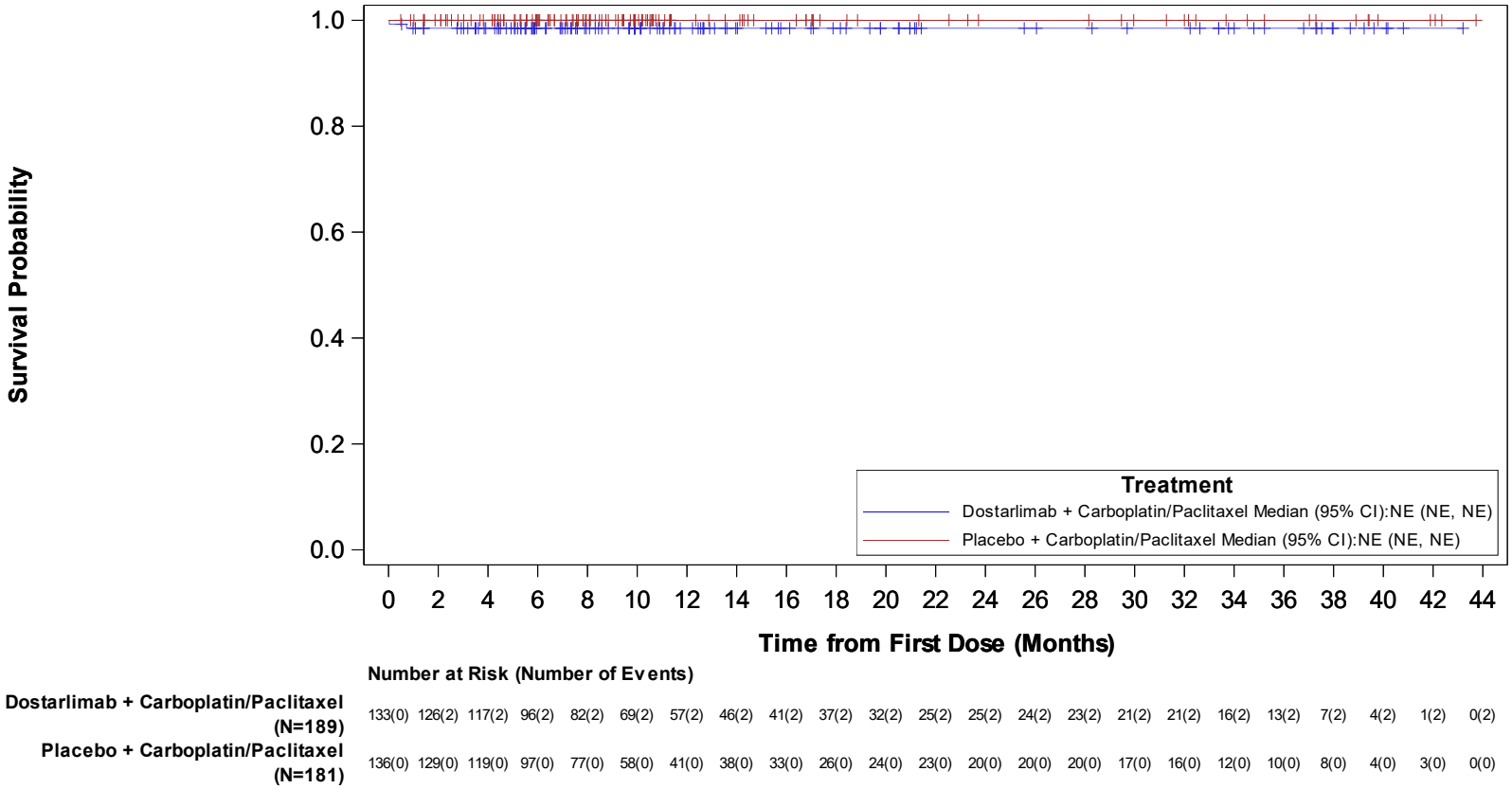
Age Group: >=65



NE = Not Estimable.
Program: f_3_7402_km_irr_ser_age.sas, Output: f_3_7402_km_irr_ser_age.rtf, Generated on: 18SEP2024 15:25,
Data Cutoff Date: 22SEP2023

Figure 3.7502 Kaplan Meier Plot of Time to Treatment-Emergent Serious Infusion-related reactions by Region (Safety Analysis Set):MMRp/MSS Subjects

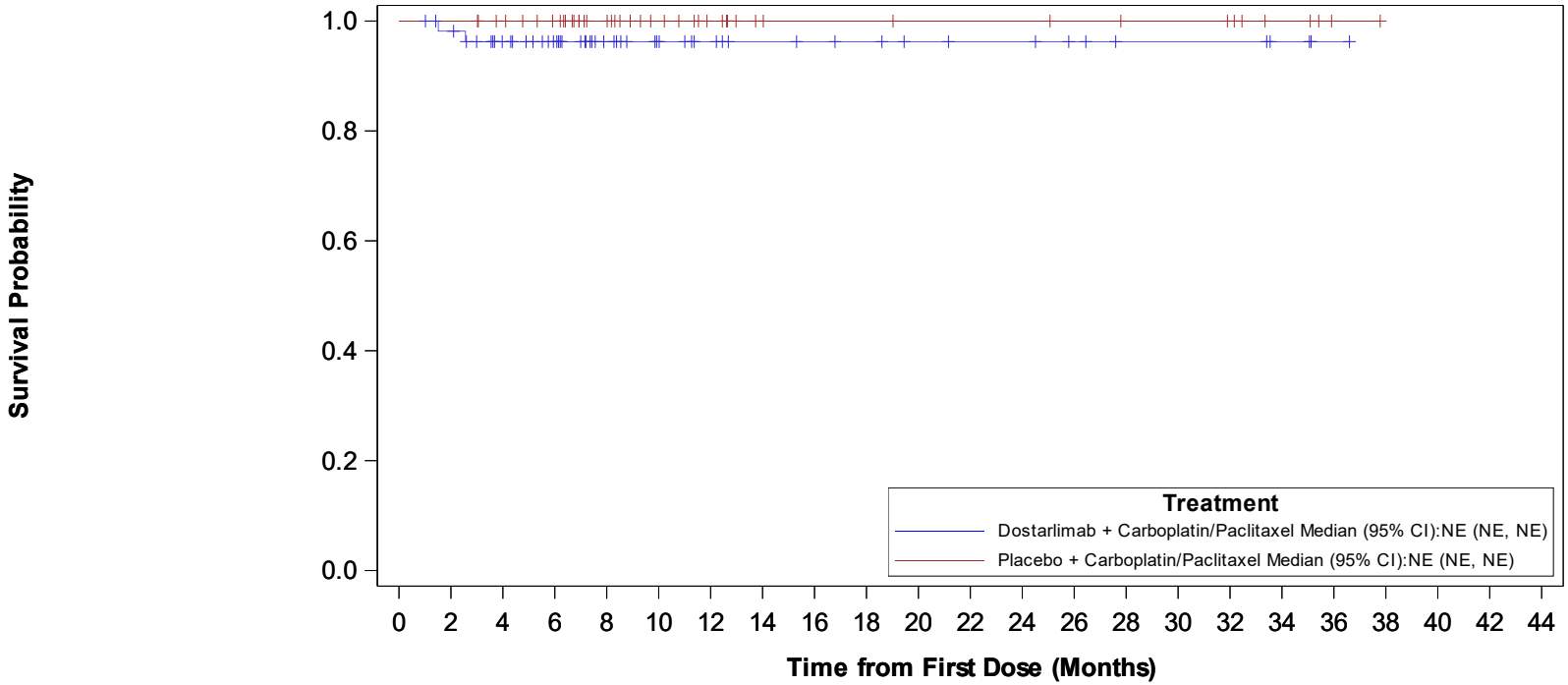
Region: North America



NE = Not Estimable.
Program: f_3_7502_km_irr_ser_reg.sas, Output: f_3_7502_km_irr_ser_reg.rtf, Generated on: 18SEP2024 15:25,
Data Cutoff Date: 22SEP2023

Figure 3.7502 Kaplan Meier Plot of Time to Treatment-Emergent Serious Infusion-related reactions by Region (Safety Analysis Set):MMRp/MSS Subjects

Region: Europe



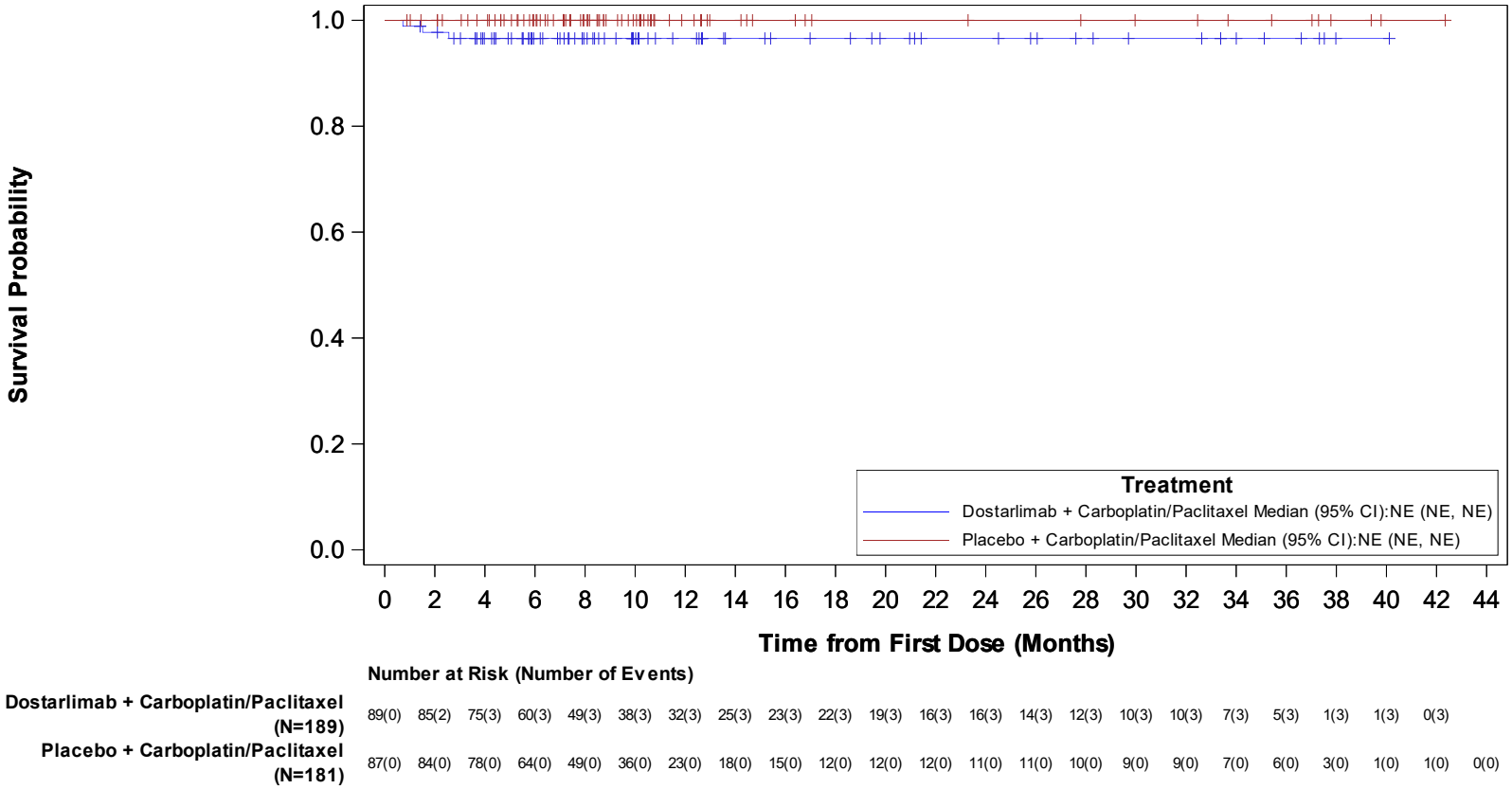
Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	56(0)	53(1)	45(2)	38(2)	27(2)	21(2)	17(2)	14(2)	13(2)	12(2)	10(2)	9(2)	9(2)	7(2)	5(2)	5(2)	5(2)	3(2)	1(2)	0(2)
Placebo + Carboplatin/Paclitaxel (N=181)	45(0)	45(0)	42(0)	38(0)	29(0)	22(0)	17(0)	12(0)	11(0)	11(0)	10(0)	10(0)	10(0)	9(0)	8(0)	8(0)	7(0)	4(0)	1(0)	0(0)

NE = Not Estimable.
Program: f_3_7502_km_irr_ser_reg.sas, Output: f_3_7502_km_irr_ser_reg.rtf, Generated on: 18SEP2024 15:25,
Data Cutoff Date: 22SEP2023

Figure 3.7602 Kaplan Meier Plot of Time to Treatment-Emergent Serious Infusion-related reactions by Disease Status (Safety Analysis Set):MMRp/MSS Subjects

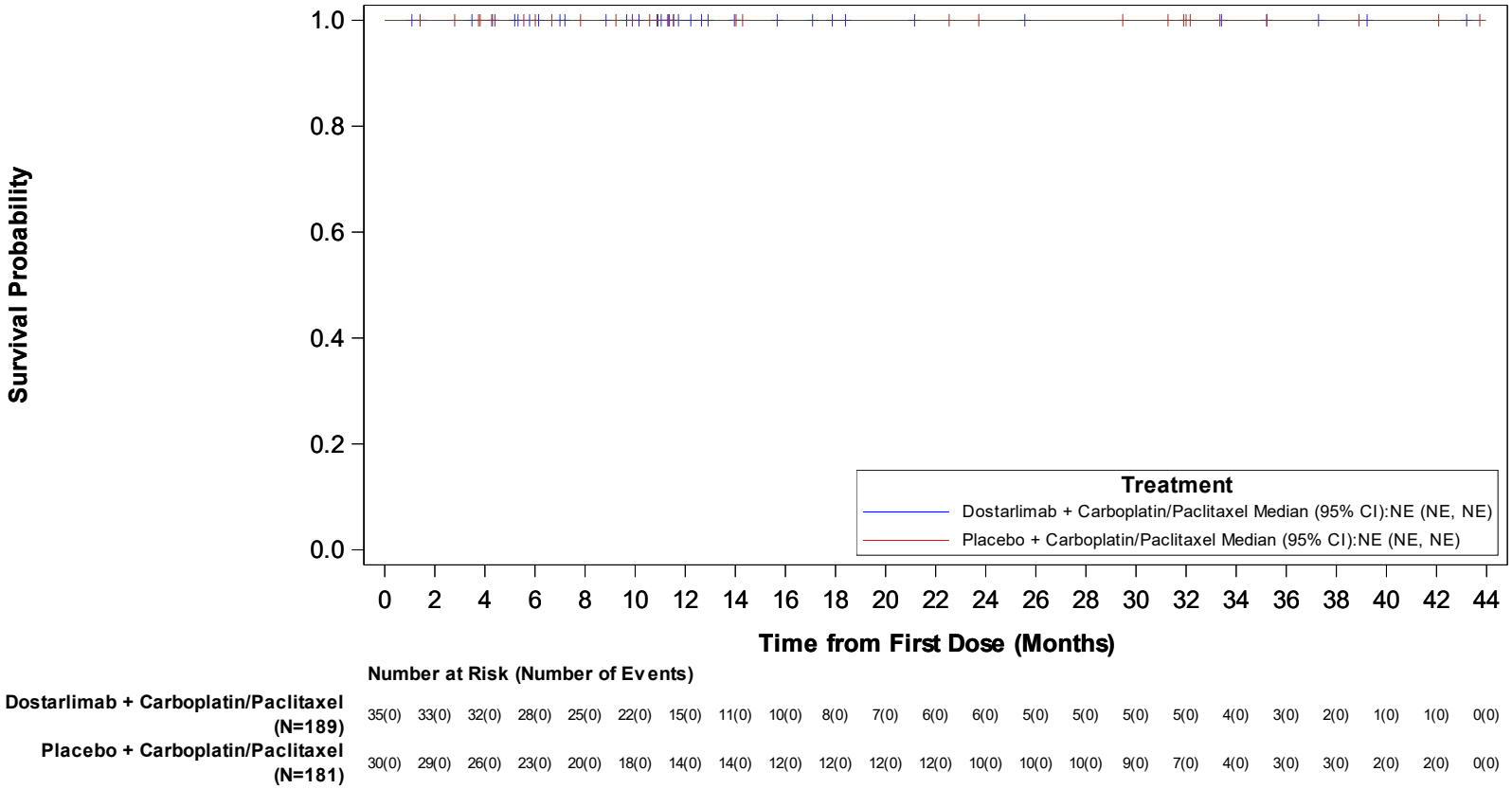
Disease Status: Recurrent



NE = Not Estimable.
Program: f_3_7602_km_irr_ser_dstat.sas, Output: f_3_7602_km_irr_ser_dstat.rtf, Generated on: 18SEP2024 15:24,
Data Cutoff Date: 22SEP2023

Figure 3.7602 Kaplan Meier Plot of Time to Treatment-Emergent Serious Infusion-related reactions by Disease Status (Safety Analysis Set):MMRp/MSS Subjects

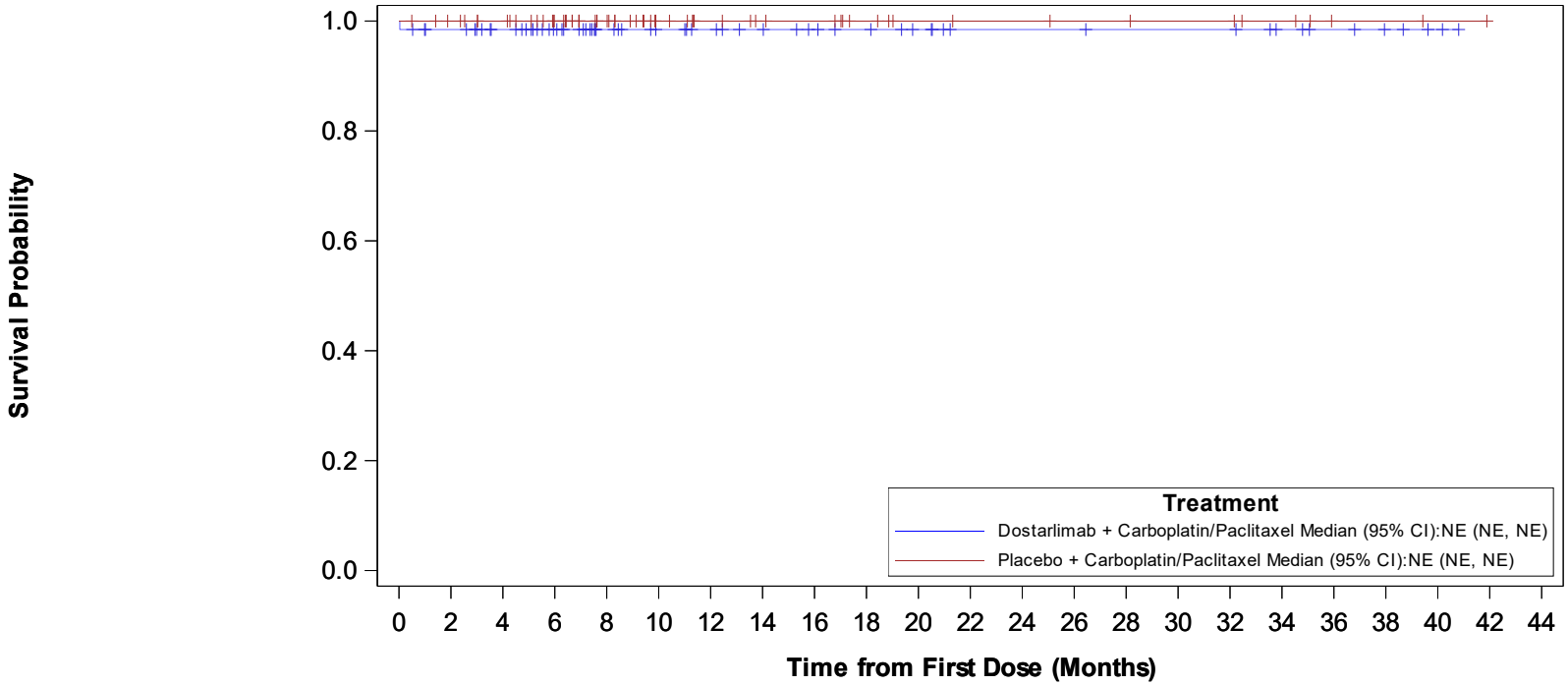
Disease Status: Primary Stage III



NE = Not Estimable.
Program: f_3_7602_km_irr_ser_dstat.sas, Output: f_3_7602_km_irr_ser_dstat.rtf, Generated on: 18SEP2024 15:24,
Data Cutoff Date: 22SEP2023

Figure 3.7602 Kaplan Meier Plot of Time to Treatment-Emergent Serious Infusion-related reactions by Disease Status (Safety Analysis Set):MMRp/MSS Subjects

Disease Status: Primary Stage IV



Number at Risk (Number of Events)

Dostarlimab + Carboplatin/Paclitaxel (N=189)	65(0)	61(1)	55(1)	46(1)	35(1)	30(1)	27(1)	24(1)	21(1)	19(1)	16(1)	12(1)	12(1)	12(1)	11(1)	11(1)	11(1)	8(1)	6(1)	4(1)	2(1)	0(1)
Placebo + Carboplatin/Paclitaxel (N=181)	64(0)	61(0)	57(0)	48(0)	37(0)	26(0)	21(0)	18(0)	17(0)	13(0)	10(0)	9(0)	9(0)	8(0)	8(0)	7(0)	7(0)	5(0)	2(0)	2(0)	1(0)	0(0)

NE = Not Estimable.
Program: f_3_7602_km_irr_ser_dstat.sas, Output: f_3_7602_km_irr_ser_dstat.rtf, Generated on: 18SEP2024 15:24,
Data Cutoff Date: 22SEP2023

Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	25 (26.0%)	9 (11.0%)
	Censored	71 (74.0%)	73 (89.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	6.0 (0.9, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
Data Cutoff Date: 22SEP2023

Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	75.8% (65.9%, 83.2%)	90.0% (81.0%, 94.9%)
	Month 12	72.4% (61.6%, 80.6%)	88.2% (78.5%, 93.7%)
	Month 18	72.4% (61.6%, 80.6%)	88.2% (78.5%, 93.7%)
	Month 24	72.4% (61.6%, 80.6%)	88.2% (78.5%, 93.7%)
	Month 30	72.4% (61.6%, 80.6%)	88.2% (78.5%, 93.7%)
	Month 36	72.4% (61.6%, 80.6%)	88.2% (78.5%, 93.7%)
	Hazard ratio[b] (95% CI)	2.58 (1.204, 5.537)	
	p-value of 2-sided stratified log-rank test	0.0115	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
Data Cutoff Date: 22SEP2023

Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	16 (17.2%)	15 (15.2%)
	Censored	77 (82.8%)	84 (84.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (16.4, NE)	NE (11.2, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
Data Cutoff Date: 22SEP2023

Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	84.5% (75.2%, 90.5%)	85.5% (76.8%, 91.2%)
	Month 12	84.5% (75.2%, 90.5%)	81.5% (68.4%, 89.5%)
	Month 18	80.5% (67.3%, 88.8%)	81.5% (68.4%, 89.5%)
	Month 24	76.0% (59.8%, 86.4%)	81.5% (68.4%, 89.5%)
	Month 30	76.0% (59.8%, 86.4%)	81.5% (68.4%, 89.5%)
	Month 36	76.0% (59.8%, 86.4%)	81.5% (68.4%, 89.5%)
	Hazard ratio[b] (95% CI)	1.10 (0.540, 2.232)	
	p-value of 2-sided stratified log-rank test	0.7964	
	p-value from Interaction Test[c]	0.1148	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
Data Cutoff Date: 22SEP2023

Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	11 (11.5%)	3 (3.7%)
	Censored	85 (88.5%)	79 (96.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (17.1, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	90.2% (81.9%, 94.8%)	96.2% (88.6%, 98.8%)
	Month 12	87.7% (77.4%, 93.5%)	96.2% (88.6%, 98.8%)
	Month 18	83.5% (69.0%, 91.6%)	96.2% (88.6%, 98.8%)
	Month 24	83.5% (69.0%, 91.6%)	96.2% (88.6%, 98.8%)
	Month 30	83.5% (69.0%, 91.6%)	96.2% (88.6%, 98.8%)
	Month 36	83.5% (69.0%, 91.6%)	96.2% (88.6%, 98.8%)
	Hazard ratio[b] (95% CI)	3.37 (0.936, 12.150)	
	p-value of 2-sided stratified log-rank test	0.0487	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	16 (17.2%)	4 (4.0%)
	Censored	77 (82.8%)	95 (96.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (6.5, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
Data Cutoff Date: 22SEP2023

Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	85.8% (76.8%, 91.5%)	95.8% (89.1%, 98.4%)
	Month 12	80.5% (69.6%, 87.8%)	95.8% (89.1%, 98.4%)
	Month 18	80.5% (69.6%, 87.8%)	95.8% (89.1%, 98.4%)
	Month 24	80.5% (69.6%, 87.8%)	95.8% (89.1%, 98.4%)
	Month 30	80.5% (69.6%, 87.8%)	95.8% (89.1%, 98.4%)
	Month 36	80.5% (69.6%, 87.8%)	95.8% (89.1%, 98.4%)
	Hazard ratio[b] (95% CI)	4.79 (1.595, 14.383)	
	p-value of 2-sided stratified log-rank test	0.0021	
	p-value from Interaction Test[c]	0.6701	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
Data Cutoff Date: 22SEP2023

Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	7 (7.3%)	4 (4.9%)
	Censored	89 (92.7%)	78 (95.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	93.7% (86.5%, 97.1%)	96.2% (88.6%, 98.8%)
	Month 12	92.1% (83.9%, 96.2%)	93.5% (82.5%, 97.7%)
	Month 18	92.1% (83.9%, 96.2%)	93.5% (82.5%, 97.7%)
	Month 24	92.1% (83.9%, 96.2%)	93.5% (82.5%, 97.7%)
	Month 30	92.1% (83.9%, 96.2%)	93.5% (82.5%, 97.7%)
	Month 36	92.1% (83.9%, 96.2%)	93.5% (82.5%, 97.7%)
	Hazard ratio[b] (95% CI)	1.46 (0.428, 5.001)	
	p-value of 2-sided stratified log-rank test	0.5412	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	12 (12.9%)	3 (3.0%)
	Censored	81 (87.1%)	96 (97.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	30.5 (16.3, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	93.1% (85.1%, 96.8%)	97.9% (91.9%, 99.5%)
	Month 12	86.0% (75.1%, 92.4%)	95.5% (85.2%, 98.7%)
	Month 18	82.5% (68.8%, 90.5%)	95.5% (85.2%, 98.7%)
	Month 24	82.5% (68.8%, 90.5%)	95.5% (85.2%, 98.7%)
	Month 30	82.5% (68.8%, 90.5%)	95.5% (85.2%, 98.7%)
	Month 36	75.0% (53.1%, 87.7%)	95.5% (85.2%, 98.7%)
	Hazard ratio[b] (95% CI)	4.15 (1.158, 14.839)	
	p-value of 2-sided stratified log-rank test	0.0182	
	p-value from Interaction Test[c]	0.2559	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	14 (14.6%)	5 (6.1%)
	Censored	82 (85.4%)	77 (93.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (11.2, NE)	NE (27.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	85.4% (76.1%, 91.3%)	95.0% (87.3%, 98.1%)
	Month 12	82.9% (72.0%, 89.8%)	95.0% (87.3%, 98.1%)
	Month 18	82.9% (72.0%, 89.8%)	95.0% (87.3%, 98.1%)
	Month 24	82.9% (72.0%, 89.8%)	95.0% (87.3%, 98.1%)
	Month 30	82.9% (72.0%, 89.8%)	90.0% (72.6%, 96.6%)
	Month 36	82.9% (72.0%, 89.8%)	90.0% (72.6%, 96.6%)
	Hazard ratio[b] (95% CI)	2.34 (0.842, 6.505)	
	p-value of 2-sided stratified log-rank test	0.0927	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	11 (11.8%)	7 (7.1%)
	Censored	82 (88.2%)	92 (92.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (15.6, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	90.8% (82.5%, 95.3%)	92.3% (84.4%, 96.3%)
	Month 12	89.4% (80.5%, 94.4%)	92.3% (84.4%, 96.3%)
	Month 18	82.3% (67.6%, 90.8%)	92.3% (84.4%, 96.3%)
	Month 24	82.3% (67.6%, 90.8%)	92.3% (84.4%, 96.3%)
	Month 30	82.3% (67.6%, 90.8%)	92.3% (84.4%, 96.3%)
	Month 36	82.3% (67.6%, 90.8%)	92.3% (84.4%, 96.3%)
	Hazard ratio[b] (95% CI)	1.66 (0.607, 4.533)	
	p-value of 2-sided stratified log-rank test	0.3189	
	p-value from Interaction Test[c]	0.5611	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	13 (13.5%)	5 (6.1%)
	Censored	83 (86.5%)	77 (93.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	16.0 (11.1, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	95.3% (87.9%, 98.2%)	95.1% (87.5%, 98.1%)
	Month 12	85.5% (73.2%, 92.4%)	95.1% (87.5%, 98.1%)
	Month 18	70.7% (52.4%, 83.0%)	92.1% (80.3%, 96.9%)
	Month 24	70.7% (52.4%, 83.0%)	92.1% (80.3%, 96.9%)
	Month 30	70.7% (52.4%, 83.0%)	92.1% (80.3%, 96.9%)
	Month 36	70.7% (52.4%, 83.0%)	92.1% (80.3%, 96.9%)
	Hazard ratio[b] (95% CI)	2.36 (0.838, 6.640)	
	p-value of 2-sided stratified log-rank test	0.0930	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	10 (10.8%)	5 (5.1%)
	Censored	83 (89.2%)	94 (94.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (15.3, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	93.0% (85.0%, 96.8%)	95.8% (89.2%, 98.4%)
	Month 12	91.5% (82.9%, 95.9%)	93.8% (85.0%, 97.5%)
	Month 18	81.9% (66.5%, 90.7%)	93.8% (85.0%, 97.5%)
	Month 24	81.9% (66.5%, 90.7%)	93.8% (85.0%, 97.5%)
	Month 30	81.9% (66.5%, 90.7%)	93.8% (85.0%, 97.5%)
	Month 36	81.9% (66.5%, 90.7%)	93.8% (85.0%, 97.5%)
	Hazard ratio[b] (95% CI)	1.97 (0.668, 5.820)	
	p-value of 2-sided stratified log-rank test	0.2102	
	p-value from Interaction Test[c]	0.7430	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	13 (13.5%)	2 (2.4%)
	Censored	83 (86.5%)	80 (97.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (11.2, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	88.9% (80.3%, 93.9%)	97.4% (90.0%, 99.3%)
	Month 12	84.3% (72.9%, 91.1%)	97.4% (90.0%, 99.3%)
	Month 18	84.3% (72.9%, 91.1%)	97.4% (90.0%, 99.3%)
	Month 24	79.3% (63.2%, 88.9%)	97.4% (90.0%, 99.3%)
	Month 30	79.3% (63.2%, 88.9%)	97.4% (90.0%, 99.3%)
	Month 36	79.3% (63.2%, 88.9%)	97.4% (90.0%, 99.3%)
	Hazard ratio[b] (95% CI)	5.69 (1.283, 25.246)	
	p-value of 2-sided stratified log-rank test	0.0097	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	11 (11.8%)	6 (6.1%)
	Censored	82 (88.2%)	93 (93.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (15.6, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	92.1% (84.0%, 96.1%)	94.2% (86.6%, 97.6%)
	Month 12	88.9% (79.5%, 94.1%)	92.7% (84.3%, 96.7%)
	Month 18	82.4% (68.2%, 90.6%)	92.7% (84.3%, 96.7%)
	Month 24	82.4% (68.2%, 90.6%)	92.7% (84.3%, 96.7%)
	Month 30	82.4% (68.2%, 90.6%)	92.7% (84.3%, 96.7%)
	Month 36	82.4% (68.2%, 90.6%)	92.7% (84.3%, 96.7%)
	Hazard ratio[b] (95% CI)	2.01 (0.689, 5.837)	
	p-value of 2-sided stratified log-rank test	0.1933	
	p-value from Interaction Test[c]	0.2064	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	14 (14.6%)	5 (6.1%)
	Censored	82 (85.4%)	77 (93.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (10.2, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	86.2% (76.9%, 91.9%)	95.7% (87.3%, 98.6%)
	Month 12	81.2% (69.1%, 88.9%)	92.3% (82.4%, 96.7%)
	Month 18	81.2% (69.1%, 88.9%)	92.3% (82.4%, 96.7%)
	Month 24	81.2% (69.1%, 88.9%)	92.3% (82.4%, 96.7%)
	Month 30	81.2% (69.1%, 88.9%)	92.3% (82.4%, 96.7%)
	Month 36	81.2% (69.1%, 88.9%)	92.3% (82.4%, 96.7%)
	Hazard ratio[b] (95% CI)	2.47 (0.888, 6.871)	
	p-value of 2-sided stratified log-rank test	0.0732	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	10 (10.8%)	5 (5.1%)
	Censored	83 (89.2%)	94 (94.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (12.5, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	93.8% (85.8%, 97.4%)	95.6% (88.7%, 98.3%)
	Month 12	88.8% (78.5%, 94.3%)	94.1% (86.1%, 97.5%)
	Month 18	86.1% (74.1%, 92.8%)	94.1% (86.1%, 97.5%)
	Month 24	79.5% (59.4%, 90.4%)	94.1% (86.1%, 97.5%)
	Month 30	79.5% (59.4%, 90.4%)	94.1% (86.1%, 97.5%)
	Month 36	79.5% (59.4%, 90.4%)	94.1% (86.1%, 97.5%)
	Hazard ratio[b] (95% CI)	2.15 (0.732, 6.334)	
	p-value of 2-sided stratified log-rank test	0.1537	
	p-value from Interaction Test[c]	0.8023	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	11 (11.5%)	4 (4.9%)
	Censored	85 (88.5%)	78 (95.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (15.0, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	92.4% (84.8%, 96.3%)	97.1% (88.8%, 99.3%)
	Month 12	89.4% (80.4%, 94.4%)	97.1% (88.8%, 99.3%)
	Month 18	82.1% (67.1%, 90.8%)	91.2% (76.8%, 96.8%)
	Month 24	82.1% (67.1%, 90.8%)	91.2% (76.8%, 96.8%)
	Month 30	82.1% (67.1%, 90.8%)	91.2% (76.8%, 96.8%)
	Month 36	82.1% (67.1%, 90.8%)	91.2% (76.8%, 96.8%)
	Hazard ratio[b] (95% CI)	2.45 (0.778, 7.747)	
	p-value of 2-sided stratified log-rank test	0.1137	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	7 (7.5%)	2 (2.0%)
	Censored	86 (92.5%)	97 (98.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	93.3% (85.6%, 96.9%)	99.0% (93.0%, 99.9%)
	Month 12	91.8% (83.4%, 96.0%)	97.5% (89.9%, 99.4%)
	Month 18	91.8% (83.4%, 96.0%)	97.5% (89.9%, 99.4%)
	Month 24	91.8% (83.4%, 96.0%)	97.5% (89.9%, 99.4%)
	Month 30	91.8% (83.4%, 96.0%)	97.5% (89.9%, 99.4%)
	Month 36	91.8% (83.4%, 96.0%)	97.5% (89.9%, 99.4%)
	Hazard ratio[b] (95% CI)	3.74 (0.772, 18.070)	
	p-value of 2-sided stratified log-rank test	0.0789	
	p-value from Interaction Test[c]	0.6664	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	2 (2.1%)	6 (7.3%)
	Censored	94 (97.9%)	76 (92.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (17.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
Data Cutoff Date: 22SEP2023

Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	97.8% (91.6%, 99.5%)	93.7% (85.6%, 97.3%)
	Month 12	97.8% (91.6%, 99.5%)	93.7% (85.6%, 97.3%)
	Month 18	97.8% (91.6%, 99.5%)	89.5% (74.7%, 95.8%)
	Month 24	97.8% (91.6%, 99.5%)	89.5% (74.7%, 95.8%)
	Month 30	97.8% (91.6%, 99.5%)	89.5% (74.7%, 95.8%)
	Month 36	97.8% (91.6%, 99.5%)	89.5% (74.7%, 95.8%)
	Hazard ratio[b] (95% CI)	0.26 (0.052, 1.275)	
	p-value of 2-sided stratified log-rank test	0.0730	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	3 (3.2%)	9 (9.1%)
	Censored	90 (96.8%)	90 (90.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (19.8, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
Data Cutoff Date: 22SEP2023

Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	97.8% (91.5%, 99.4%)	91.6% (83.8%, 95.7%)
	Month 12	97.8% (91.5%, 99.4%)	90.2% (81.8%, 94.8%)
	Month 18	97.8% (91.5%, 99.4%)	90.2% (81.8%, 94.8%)
	Month 24	92.9% (73.5%, 98.3%)	90.2% (81.8%, 94.8%)
	Month 30	92.9% (73.5%, 98.3%)	90.2% (81.8%, 94.8%)
	Month 36	92.9% (73.5%, 98.3%)	90.2% (81.8%, 94.8%)
	Hazard ratio[b] (95% CI)	0.35 (0.093, 1.291)	
	p-value of 2-sided stratified log-rank test	0.0980	
	p-value from Interaction Test[c]	0.7751	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Pneumonia

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	7 (7.3%)	2 (2.4%)
	Censored	89 (92.7%)	80 (97.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (24.4, NE)	NE (26.3, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Pneumonia

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	93.4% (86.0%, 97.0%)	100% (100%, 100%)
	Month 12	93.4% (86.0%, 97.0%)	100% (100%, 100%)
	Month 18	93.4% (86.0%, 97.0%)	97.0% (80.4%, 99.6%)
	Month 24	93.4% (86.0%, 97.0%)	97.0% (80.4%, 99.6%)
	Month 30	88.2% (71.3%, 95.5%)	91.9% (70.0%, 98.0%)
	Month 36	88.2% (71.3%, 95.5%)	91.9% (70.0%, 98.0%)
	Hazard ratio[b] (95% CI)	3.91 (0.785, 19.503)	
	p-value of 2-sided stratified log-rank test	0.0752	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Pneumonia

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	3 (3.2%)	0
	Censored	90 (96.8%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypocalcaemia

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	4 (4.2%)	1 (1.2%)
	Censored	92 (95.8%)	81 (98.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypocalcaemia

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	96.9% (90.6%, 99.0%)	98.8% (91.6%, 99.8%)
	Month 12	94.9% (86.5%, 98.2%)	98.8% (91.6%, 99.8%)
	Month 18	94.9% (86.5%, 98.2%)	98.8% (91.6%, 99.8%)
	Month 24	94.9% (86.5%, 98.2%)	98.8% (91.6%, 99.8%)
	Month 30	94.9% (86.5%, 98.2%)	98.8% (91.6%, 99.8%)
	Month 36	94.9% (86.5%, 98.2%)	98.8% (91.6%, 99.8%)
	Hazard ratio[b] (95% CI)	3.41 (0.381, 30.493)	
	p-value of 2-sided stratified log-rank test	0.2435	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypocalcaemia

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	5 (5.4%)	1 (1.0%)
	Censored	88 (94.6%)	98 (99.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypocalcaemia

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	94.4% (87.1%, 97.6%)	99.0% (93.0%, 99.9%)
	Month 12	94.4% (87.1%, 97.6%)	99.0% (93.0%, 99.9%)
	Month 18	94.4% (87.1%, 97.6%)	99.0% (93.0%, 99.9%)
	Month 24	94.4% (87.1%, 97.6%)	99.0% (93.0%, 99.9%)
	Month 30	94.4% (87.1%, 97.6%)	99.0% (93.0%, 99.9%)
	Month 36	94.4% (87.1%, 97.6%)	99.0% (93.0%, 99.9%)
	Hazard ratio[b] (95% CI)	5.65 (0.658, 48.570)	
	p-value of 2-sided stratified log-rank test	0.0752	
	p-value from Interaction Test[c]	0.7425	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Pollakiuria

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	6 (6.3%)	1 (1.2%)
	Censored	90 (93.8%)	81 (98.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (28.9, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Pollakiuria

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	95.8% (89.3%, 98.4%)	98.7% (90.9%, 99.8%)
	Month 12	93.8% (85.2%, 97.5%)	98.7% (90.9%, 99.8%)
	Month 18	93.8% (85.2%, 97.5%)	98.7% (90.9%, 99.8%)
	Month 24	93.8% (85.2%, 97.5%)	98.7% (90.9%, 99.8%)
	Month 30	87.6% (66.8%, 95.7%)	98.7% (90.9%, 99.8%)
	Month 36	87.6% (66.8%, 95.7%)	98.7% (90.9%, 99.8%)
	Hazard ratio[b] (95% CI)	8.64 (0.896, 83.331)	
	p-value of 2-sided stratified log-rank test	0.0347	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
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Table 3.0602 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Pollakiuria

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	4 (4.3%)	0
	Censored	89 (95.7%)	99 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0602_ttae_socpt_age.sas, Output: t_3_0602_ttae_socpt_age.rtf, Generated on: 03SEP2024 14:12,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	30 (22.6%)	21 (15.4%)
	Censored	103 (77.4%)	115 (84.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	16.4 (1.4, NE)	NE (11.2, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	79.3% (71.2%, 85.3%)	85.6% (78.4%, 90.6%)
	Month 12	77.0% (68.4%, 83.5%)	82.2% (73.0%, 88.5%)
	Month 18	74.4% (64.4%, 82.0%)	82.2% (73.0%, 88.5%)
	Month 24	74.4% (64.4%, 82.0%)	82.2% (73.0%, 88.5%)
	Month 30	74.4% (64.4%, 82.0%)	82.2% (73.0%, 88.5%)
	Month 36	74.4% (64.4%, 82.0%)	82.2% (73.0%, 88.5%)
	Hazard ratio[b] (95% CI)	1.50 (0.854, 2.622)	
	p-value of 2-sided stratified log-rank test	0.1568	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	11 (19.6%)	3 (6.7%)
	Censored	45 (80.4%)	42 (93.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	18.7 (0.9, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	81.9% (68.9%, 89.8%)	93.1% (80.1%, 97.7%)
	Month 12	81.9% (68.9%, 89.8%)	93.1% (80.1%, 97.7%)
	Month 18	81.9% (68.9%, 89.8%)	93.1% (80.1%, 97.7%)
	Month 24	73.7% (51.1%, 87.1%)	93.1% (80.1%, 97.7%)
	Month 30	73.7% (51.1%, 87.1%)	93.1% (80.1%, 97.7%)
	Month 36	73.7% (51.1%, 87.1%)	93.1% (80.1%, 97.7%)
	Hazard ratio[b] (95% CI)	3.68 (1.003, 13.484)	
	p-value of 2-sided stratified log-rank test	0.0365	
	p-value from Interaction Test[c]	0.2568	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	25 (18.8%)	6 (4.4%)
	Censored	108 (81.2%)	130 (95.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (7.4, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	84.5% (77.0%, 89.7%)	95.3% (89.8%, 97.9%)
	Month 12	79.2% (70.1%, 85.8%)	95.3% (89.8%, 97.9%)
	Month 18	76.4% (65.5%, 84.2%)	95.3% (89.8%, 97.9%)
	Month 24	76.4% (65.5%, 84.2%)	95.3% (89.8%, 97.9%)
	Month 30	76.4% (65.5%, 84.2%)	95.3% (89.8%, 97.9%)
	Month 36	76.4% (65.5%, 84.2%)	95.3% (89.8%, 97.9%)
	Hazard ratio[b] (95% CI)	4.50 (1.842, 10.973)	
	p-value of 2-sided stratified log-rank test	0.0003	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	2 (3.6%)	1 (2.2%)
	Censored	54 (96.4%)	44 (97.8%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	16 (12.0%)	7 (5.1%)
	Censored	117 (88.0%)	129 (94.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (16.3, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	92.9% (86.8%, 96.3%)	96.2% (91.0%, 98.4%)
	Month 12	87.1% (78.8%, 92.3%)	92.6% (84.1%, 96.7%)
	Month 18	84.5% (74.4%, 90.9%)	92.6% (84.1%, 96.7%)
	Month 24	84.5% (74.4%, 90.9%)	92.6% (84.1%, 96.7%)
	Month 30	84.5% (74.4%, 90.9%)	92.6% (84.1%, 96.7%)
	Month 36	79.8% (64.9%, 88.9%)	92.6% (84.1%, 96.7%)
	Hazard ratio[b] (95% CI)	2.21 (0.901, 5.395)	
	p-value of 2-sided stratified log-rank test	0.0758	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	3 (5.4%)	0
	Censored	53 (94.6%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	19 (14.3%)	11 (8.1%)
	Censored	114 (85.7%)	125 (91.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (15.6, NE)	NE (27.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	88.1% (81.0%, 92.7%)	92.1% (85.7%, 95.7%)
	Month 12	85.5% (77.4%, 90.9%)	92.1% (85.7%, 95.7%)
	Month 18	80.8% (70.0%, 88.1%)	92.1% (85.7%, 95.7%)
	Month 24	80.8% (70.0%, 88.1%)	92.1% (85.7%, 95.7%)
	Month 30	80.8% (70.0%, 88.1%)	86.9% (71.3%, 94.4%)
	Month 36	80.8% (70.0%, 88.1%)	86.9% (71.3%, 94.4%)
	Hazard ratio[b] (95% CI)	1.79 (0.828, 3.848)	
	p-value of 2-sided stratified log-rank test	0.1335	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	6 (10.7%)	1 (2.2%)
	Censored	50 (89.3%)	44 (97.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (5.9, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	87.9% (74.8%, 94.4%)	97.6% (83.9%, 99.7%)
	Month 12	87.9% (74.8%, 94.4%)	97.6% (83.9%, 99.7%)
	Month 18	87.9% (74.8%, 94.4%)	97.6% (83.9%, 99.7%)
	Month 24	87.9% (74.8%, 94.4%)	97.6% (83.9%, 99.7%)
	Month 30	87.9% (74.8%, 94.4%)	97.6% (83.9%, 99.7%)
	Month 36	87.9% (74.8%, 94.4%)	97.6% (83.9%, 99.7%)
	Hazard ratio[b] (95% CI)	6.38 (0.753, 53.996)	
	p-value of 2-sided stratified log-rank test	0.0530	
	p-value from Interaction Test[c]	0.2337	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	20 (15.0%)	9 (6.6%)
	Censored	113 (85.0%)	127 (93.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	17.9 (13.5, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	93.4% (87.1%, 96.6%)	94.7% (89.2%, 97.4%)
	Month 12	86.1% (77.4%, 91.7%)	93.3% (86.7%, 96.7%)
	Month 18	72.5% (58.9%, 82.3%)	90.7% (81.1%, 95.6%)
	Month 24	72.5% (58.9%, 82.3%)	90.7% (81.1%, 95.6%)
	Month 30	72.5% (58.9%, 82.3%)	90.7% (81.1%, 95.6%)
	Month 36	72.5% (58.9%, 82.3%)	90.7% (81.1%, 95.6%)
	Hazard ratio[b] (95% CI)	2.05 (0.931, 4.515)	
	p-value of 2-sided stratified log-rank test	0.0682	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	3 (5.4%)	1 (2.2%)
	Censored	53 (94.6%)	44 (97.8%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	22 (16.5%)	8 (5.9%)
	Censored	111 (83.5%)	128 (94.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (11.2, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	88.1% (81.1%, 92.7%)	94.0% (87.8%, 97.1%)
	Month 12	83.1% (74.4%, 89.1%)	92.9% (86.1%, 96.4%)
	Month 18	78.5% (67.5%, 86.2%)	92.9% (86.1%, 96.4%)
	Month 24	75.1% (62.1%, 84.2%)	92.9% (86.1%, 96.4%)
	Month 30	75.1% (62.1%, 84.2%)	92.9% (86.1%, 96.4%)
	Month 36	75.1% (62.1%, 84.2%)	92.9% (86.1%, 96.4%)
	Hazard ratio[b] (95% CI)	3.07 (1.309, 7.216)	
	p-value of 2-sided stratified log-rank test	0.0067	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	2 (3.6%)	0
	Censored	54 (96.4%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	15 (11.3%)	9 (6.6%)
	Censored	118 (88.7%)	127 (93.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (21.4, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	90.8% (84.0%, 94.8%)	94.1% (88.1%, 97.2%)
	Month 12	87.7% (79.2%, 92.8%)	91.9% (85.0%, 95.8%)
	Month 18	85.9% (76.6%, 91.7%)	91.9% (85.0%, 95.8%)
	Month 24	81.4% (67.1%, 89.9%)	91.9% (85.0%, 95.8%)
	Month 30	81.4% (67.1%, 89.9%)	91.9% (85.0%, 95.8%)
	Month 36	81.4% (67.1%, 89.9%)	91.9% (85.0%, 95.8%)
	Hazard ratio[b] (95% CI)	1.69 (0.738, 3.881)	
	p-value of 2-sided stratified log-rank test	0.2080	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	9 (16.1%)	1 (2.2%)
	Censored	47 (83.9%)	44 (97.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (4.8, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	87.3% (73.9%, 94.1%)	100% (100%, 100%)
	Month 12	77.2% (59.6%, 87.9%)	97.0% (80.4%, 99.6%)
	Month 18	77.2% (59.6%, 87.9%)	97.0% (80.4%, 99.6%)
	Month 24	77.2% (59.6%, 87.9%)	97.0% (80.4%, 99.6%)
	Month 30	77.2% (59.6%, 87.9%)	97.0% (80.4%, 99.6%)
	Month 36	77.2% (59.6%, 87.9%)	97.0% (80.4%, 99.6%)
	Hazard ratio[b] (95% CI)	9.03 (1.132, 72.054)	
	p-value of 2-sided stratified log-rank test	0.0122	
	p-value from Interaction Test[c]	0.1403	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	17 (12.8%)	6 (4.4%)
	Censored	116 (87.2%)	130 (95.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (16.9, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	90.6% (84.0%, 94.5%)	97.5% (92.5%, 99.2%)
	Month 12	87.5% (80.0%, 92.3%)	96.4% (90.6%, 98.7%)
	Month 18	82.7% (71.9%, 89.6%)	91.4% (79.9%, 96.5%)
	Month 24	82.7% (71.9%, 89.6%)	91.4% (79.9%, 96.5%)
	Month 30	82.7% (71.9%, 89.6%)	91.4% (79.9%, 96.5%)
	Month 36	82.7% (71.9%, 89.6%)	91.4% (79.9%, 96.5%)
	Hazard ratio[b] (95% CI)	2.67 (1.048, 6.794)	
	p-value of 2-sided stratified log-rank test	0.0321	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	1 (1.8%)	0
	Censored	55 (98.2%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	5 (3.8%)	6 (4.4%)
	Censored	128 (96.2%)	130 (95.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	96.9% (92.0%, 98.8%)	97.0% (92.1%, 98.8%)
	Month 12	96.9% (92.0%, 98.8%)	95.9% (90.2%, 98.3%)
	Month 18	96.9% (92.0%, 98.8%)	92.0% (78.6%, 97.2%)
	Month 24	93.9% (82.7%, 97.9%)	92.0% (78.6%, 97.2%)
	Month 30	93.9% (82.7%, 97.9%)	92.0% (78.6%, 97.2%)
	Month 36	93.9% (82.7%, 97.9%)	92.0% (78.6%, 97.2%)
	Hazard ratio[b] (95% CI)	0.81 (0.246, 2.668)	
	p-value of 2-sided stratified log-rank test	0.7291	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	0	9 (20.0%)
	Censored	56 (100%)	36 (80.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (1.0, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	100% (100%, 100%)	79.6% (64.3%, 88.8%)
	Month 12	100% (100%, 100%)	79.6% (64.3%, 88.8%)
	Month 18	100% (100%, 100%)	79.6% (64.3%, 88.8%)
	Month 24	100% (100%, 100%)	79.6% (64.3%, 88.8%)
	Month 30	100% (100%, 100%)	79.6% (64.3%, 88.8%)
	Month 36	100% (100%, 100%)	NE (NE, NE)
	Hazard ratio[b] (95% CI)	- (-,-)	
	p-value of 2-sided stratified log-rank test	0.0011	
	p-value from Interaction Test[c]	0.9884	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Pneumonia

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	7 (5.3%)	1 (0.7%)
	Censored	126 (94.7%)	135 (99.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Pneumonia

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	95.3% (89.8%, 97.9%)	100% (100%, 100%)
	Month 12	95.3% (89.8%, 97.9%)	100% (100%, 100%)
	Month 18	93.3% (85.5%, 97.0%)	97.4% (83.2%, 99.6%)
	Month 24	93.3% (85.5%, 97.0%)	97.4% (83.2%, 99.6%)
	Month 30	93.3% (85.5%, 97.0%)	97.4% (83.2%, 99.6%)
	Month 36	93.3% (85.5%, 97.0%)	97.4% (83.2%, 99.6%)
	Hazard ratio[b] (95% CI)	7.07 (0.868, 57.636)	
	p-value of 2-sided stratified log-rank test	0.0332	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Pneumonia

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	3 (5.4%)	1 (2.2%)
	Censored	53 (94.6%)	44 (97.8%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypocalcaemia

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	6 (4.5%)	2 (1.5%)
	Censored	127 (95.5%)	134 (98.5%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypocalcaemia

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	96.1% (90.9%, 98.4%)	98.5% (94.2%, 99.6%)
	Month 12	94.8% (88.6%, 97.7%)	98.5% (94.2%, 99.6%)
	Month 18	94.8% (88.6%, 97.7%)	98.5% (94.2%, 99.6%)
	Month 24	94.8% (88.6%, 97.7%)	98.5% (94.2%, 99.6%)
	Month 30	94.8% (88.6%, 97.7%)	98.5% (94.2%, 99.6%)
	Month 36	94.8% (88.6%, 97.7%)	98.5% (94.2%, 99.6%)
	Hazard ratio[b] (95% CI)	2.99 (0.602, 14.895)	
	p-value of 2-sided stratified log-rank test	0.1596	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypocalcaemia

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	3 (5.4%)	0
	Censored	53 (94.6%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Pollakiuria

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	8 (6.0%)	1 (0.7%)
	Censored	125 (94.0%)	135 (99.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (28.9, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Pollakiuria

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	96.2% (91.1%, 98.4%)	99.2% (94.4%, 99.9%)
	Month 12	93.6% (86.8%, 97.0%)	99.2% (94.4%, 99.9%)
	Month 18	93.6% (86.8%, 97.0%)	99.2% (94.4%, 99.9%)
	Month 24	93.6% (86.8%, 97.0%)	99.2% (94.4%, 99.9%)
	Month 30	89.2% (74.5%, 95.7%)	99.2% (94.4%, 99.9%)
	Month 36	89.2% (74.5%, 95.7%)	99.2% (94.4%, 99.9%)
	Hazard ratio[b] (95% CI)	8.11 (1.007, 65.360)	
	p-value of 2-sided stratified log-rank test	0.0196	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
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Table 3.0702 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Pollakiuria

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	2 (3.6%)	0
	Censored	54 (96.4%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0702_ttae_socpt_reg.sas, Output: t_3_0702_ttae_socpt_reg.rtf, Generated on: 03SEP2024 14:16,
Data Cutoff Date: 22SEP2023

Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	18 (20.2%)	11 (12.6%)
	Censored	71 (79.8%)	76 (87.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (2.3, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0802_ttae_socpt_dstat.sas, Output: t_3_0802_ttae_socpt_dstat.rtf, Generated on: 03SEP2024 14:20,
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	81.6% (71.7%, 88.3%)	87.2% (78.1%, 92.7%)
	Month 12	80.0% (69.7%, 87.1%)	87.2% (78.1%, 92.7%)
	Month 18	75.8% (62.0%, 85.2%)	87.2% (78.1%, 92.7%)
	Month 24	75.8% (62.0%, 85.2%)	87.2% (78.1%, 92.7%)
	Month 30	75.8% (62.0%, 85.2%)	87.2% (78.1%, 92.7%)
	Month 36	75.8% (62.0%, 85.2%)	87.2% (78.1%, 92.7%)
	Hazard ratio[b] (95% CI)	1.59 (0.748, 3.365)	
	p-value of 2-sided stratified log-rank test	0.2251	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0802_ttae_socpt_dstat.sas, Output: t_3_0802_ttae_socpt_dstat.rtf, Generated on: 03SEP2024 14:20,
Data Cutoff Date: 22SEP2023

Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	12 (34.3%)	4 (13.3%)
	Censored	23 (65.7%)	26 (86.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	0.4 (0.2, NE)	NE (2.1, NE)
	50%	NE (9.7, NE)	NE (NE, NE)
	75%	NE (18.7, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	71.4% (53.4%, 83.5%)	86.0% (66.7%, 94.5%)
	Month 12	67.2% (48.3%, 80.5%)	86.0% (66.7%, 94.5%)
	Month 18	67.2% (48.3%, 80.5%)	86.0% (66.7%, 94.5%)
	Month 24	50.4% (18.6%, 75.7%)	86.0% (66.7%, 94.5%)
	Month 30	50.4% (18.6%, 75.7%)	86.0% (66.7%, 94.5%)
	Month 36	50.4% (18.6%, 75.7%)	86.0% (66.7%, 94.5%)
	Hazard ratio[b] (95% CI)	3.03 (0.965, 9.484)	
	p-value of 2-sided stratified log-rank test	0.0465	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	11 (16.9%)	9 (14.1%)
	Censored	54 (83.1%)	55 (85.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (0.9, NE)	NE (6.9, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	82.6% (70.7%, 90.0%)	88.5% (77.4%, 94.4%)
	Month 12	82.6% (70.7%, 90.0%)	82.0% (66.3%, 90.8%)
	Month 18	82.6% (70.7%, 90.0%)	82.0% (66.3%, 90.8%)
	Month 24	82.6% (70.7%, 90.0%)	82.0% (66.3%, 90.8%)
	Month 30	82.6% (70.7%, 90.0%)	82.0% (66.3%, 90.8%)
	Month 36	82.6% (70.7%, 90.0%)	82.0% (66.3%, 90.8%)
	Hazard ratio[b] (95% CI)	1.29 (0.535, 3.117)	
	p-value of 2-sided stratified log-rank test	0.5722	
	p-value from Interaction Test[c]	0.4579	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	9 (10.1%)	4 (4.6%)
	Censored	80 (89.9%)	83 (95.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	90.9% (82.6%, 95.3%)	95.3% (87.9%, 98.2%)
	Month 12	89.1% (79.8%, 94.2%)	95.3% (87.9%, 98.2%)
	Month 18	89.1% (79.8%, 94.2%)	95.3% (87.9%, 98.2%)
	Month 24	89.1% (79.8%, 94.2%)	95.3% (87.9%, 98.2%)
	Month 30	89.1% (79.8%, 94.2%)	95.3% (87.9%, 98.2%)
	Month 36	89.1% (79.8%, 94.2%)	95.3% (87.9%, 98.2%)
	Hazard ratio[b] (95% CI)	2.29 (0.705, 7.451)	
	p-value of 2-sided stratified log-rank test	0.1559	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	5 (14.3%)	0
	Censored	30 (85.7%)	30 (100%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (10.8, NE)	NE (NE, NE)
	50%	NE (17.1, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	91.2% (75.2%, 97.1%)	100% (100%, 100%)
	Month 12	86.4% (66.8%, 94.9%)	100% (100%, 100%)
	Month 18	75.6% (44.0%, 90.9%)	100% (100%, 100%)
	Month 24	75.6% (44.0%, 90.9%)	100% (100%, 100%)
	Month 30	75.6% (44.0%, 90.9%)	100% (100%, 100%)
	Month 36	75.6% (44.0%, 90.9%)	100% (100%, 100%)
	Hazard ratio[b] (95% CI)	- (-,-)	
	p-value of 2-sided stratified log-rank test	0.0293	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	13 (20.0%)	3 (4.7%)
	Censored	52 (80.0%)	61 (95.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (1.4, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Rash maculo-papular

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	82.3% (70.1%, 89.8%)	95.0% (85.2%, 98.3%)
	Month 12	76.4% (61.8%, 86.0%)	95.0% (85.2%, 98.3%)
	Month 18	76.4% (61.8%, 86.0%)	95.0% (85.2%, 98.3%)
	Month 24	76.4% (61.8%, 86.0%)	95.0% (85.2%, 98.3%)
	Month 30	76.4% (61.8%, 86.0%)	95.0% (85.2%, 98.3%)
	Month 36	76.4% (61.8%, 86.0%)	95.0% (85.2%, 98.3%)
	Hazard ratio[b] (95% CI)	4.80 (1.368, 16.862)	
	p-value of 2-sided stratified log-rank test	0.0068	
	p-value from Interaction Test[c]	0.7069	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	8 (9.0%)	4 (4.6%)
	Censored	81 (91.0%)	83 (95.4%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (30.5, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	94.3% (86.9%, 97.6%)	97.7% (91.0%, 99.4%)
	Month 12	90.3% (80.1%, 95.4%)	91.6% (77.1%, 97.1%)
	Month 18	90.3% (80.1%, 95.4%)	91.6% (77.1%, 97.1%)
	Month 24	90.3% (80.1%, 95.4%)	91.6% (77.1%, 97.1%)
	Month 30	90.3% (80.1%, 95.4%)	91.6% (77.1%, 97.1%)
	Month 36	81.3% (54.7%, 93.1%)	91.6% (77.1%, 97.1%)
	Hazard ratio[b] (95% CI)	1.83 (0.548, 6.136)	
	p-value of 2-sided stratified log-rank test	0.3186	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	7 (20.0%)	0
	Censored	28 (80.0%)	30 (100%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	16.3 (5.5, NE)	NE (NE, NE)
	50%	NE (16.3, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	90.6% (73.5%, 96.9%)	100% (100%, 100%)
	Month 12	78.6% (57.9%, 89.9%)	100% (100%, 100%)
	Month 18	68.8% (40.7%, 85.5%)	100% (100%, 100%)
	Month 24	68.8% (40.7%, 85.5%)	100% (100%, 100%)
	Month 30	68.8% (40.7%, 85.5%)	100% (100%, 100%)
	Month 36	68.8% (40.7%, 85.5%)	100% (100%, 100%)
	Hazard ratio[b] (95% CI)	- (-,-)	
	p-value of 2-sided stratified log-rank test	0.0107	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0802_ttae_socpt_dstat.sas, Output: t_3_0802_ttae_socpt_dstat.rtf, Generated on: 03SEP2024 14:20,
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	4 (6.2%)	3 (4.7%)
	Censored	61 (93.8%)	61 (95.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Skin and subcutaneous tissue disorders
Preferred Term: Dry skin

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	93.8% (84.3%, 97.6%)	95.1% (85.5%, 98.4%)
	Month 12	93.8% (84.3%, 97.6%)	95.1% (85.5%, 98.4%)
	Month 18	93.8% (84.3%, 97.6%)	95.1% (85.5%, 98.4%)
	Month 24	93.8% (84.3%, 97.6%)	95.1% (85.5%, 98.4%)
	Month 30	93.8% (84.3%, 97.6%)	95.1% (85.5%, 98.4%)
	Month 36	93.8% (84.3%, 97.6%)	95.1% (85.5%, 98.4%)
	Hazard ratio[b] (95% CI)	1.38 (0.309, 6.178)	
	p-value of 2-sided stratified log-rank test	0.6722	
	p-value from Interaction Test[c]	0.9423	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	10 (11.2%)	5 (5.7%)
	Censored	79 (88.8%)	82 (94.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (15.6, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	89.1% (80.0%, 94.2%)	94.2% (86.6%, 97.5%)
	Month 12	89.1% (80.0%, 94.2%)	94.2% (86.6%, 97.5%)
	Month 18	85.1% (71.4%, 92.5%)	94.2% (86.6%, 97.5%)
	Month 24	85.1% (71.4%, 92.5%)	94.2% (86.6%, 97.5%)
	Month 30	85.1% (71.4%, 92.5%)	94.2% (86.6%, 97.5%)
	Month 36	85.1% (71.4%, 92.5%)	94.2% (86.6%, 97.5%)
	Hazard ratio[b] (95% CI)	1.86 (0.635, 5.460)	
	p-value of 2-sided stratified log-rank test	0.2498	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	5 (14.3%)	4 (13.3%)
	Censored	30 (85.7%)	26 (86.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (3.4, NE)	NE (4.6, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	85.2% (68.0%, 93.6%)	84.5% (63.5%, 94.0%)
	Month 12	85.2% (68.0%, 93.6%)	84.5% (63.5%, 94.0%)
	Month 18	85.2% (68.0%, 93.6%)	84.5% (63.5%, 94.0%)
	Month 24	85.2% (68.0%, 93.6%)	84.5% (63.5%, 94.0%)
	Month 30	85.2% (68.0%, 93.6%)	84.5% (63.5%, 94.0%)
	Month 36	85.2% (68.0%, 93.6%)	84.5% (63.5%, 94.0%)
	Hazard ratio[b] (95% CI)	1.37 (0.327, 5.724)	
	p-value of 2-sided stratified log-rank test	0.6671	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	10 (15.4%)	3 (4.7%)
	Censored	55 (84.6%)	61 (95.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (6.8, NE)	NE (27.7, NE)
	50%	NE (NE, NE)	NE (27.7, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Alanine aminotransferase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	88.3% (76.9%, 94.3%)	96.5% (86.6%, 99.1%)
	Month 12	83.1% (69.4%, 91.1%)	96.5% (86.6%, 99.1%)
	Month 18	78.8% (62.1%, 88.7%)	96.5% (86.6%, 99.1%)
	Month 24	78.8% (62.1%, 88.7%)	96.5% (86.6%, 99.1%)
	Month 30	78.8% (62.1%, 88.7%)	84.4% (44.1%, 96.6%)
	Month 36	78.8% (62.1%, 88.7%)	84.4% (44.1%, 96.6%)
	Hazard ratio[b] (95% CI)	3.25 (0.894, 11.833)	
	p-value of 2-sided stratified log-rank test	0.0579	
	p-value from Interaction Test[c]	0.6122	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	8 (9.0%)	6 (6.9%)
	Censored	81 (91.0%)	81 (93.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (16.0, NE)	NE (13.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	92.3% (83.5%, 96.5%)	94.1% (86.4%, 97.5%)
	Month 12	92.3% (83.5%, 96.5%)	94.1% (86.4%, 97.5%)
	Month 18	84.3% (67.6%, 92.8%)	88.6% (70.1%, 95.9%)
	Month 24	84.3% (67.6%, 92.8%)	88.6% (70.1%, 95.9%)
	Month 30	84.3% (67.6%, 92.8%)	88.6% (70.1%, 95.9%)
	Month 36	84.3% (67.6%, 92.8%)	88.6% (70.1%, 95.9%)
	Hazard ratio[b] (95% CI)	1.16 (0.400, 3.359)	
	p-value of 2-sided stratified log-rank test	0.7858	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	8 (22.9%)	0
	Censored	27 (77.1%)	30 (100%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	13.5 (7.3, NE)	NE (NE, NE)
	50%	NE (13.5, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	97.1% (81.4%, 99.6%)	100% (100%, 100%)
	Month 12	77.2% (55.8%, 89.1%)	100% (100%, 100%)
	Month 18	60.8% (33.3%, 79.8%)	100% (100%, 100%)
	Month 24	60.8% (33.3%, 79.8%)	100% (100%, 100%)
	Month 30	60.8% (33.3%, 79.8%)	100% (100%, 100%)
	Month 36	60.8% (33.3%, 79.8%)	100% (100%, 100%)
	Hazard ratio[b] (95% CI)	- (-,-)	
	p-value of 2-sided stratified log-rank test	0.0052	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	7 (10.8%)	4 (6.3%)
	Censored	58 (89.2%)	60 (93.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (14.1, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Blood creatinine increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	95.0% (85.3%, 98.4%)	95.2% (85.9%, 98.4%)
	Month 12	91.5% (77.4%, 96.9%)	92.1% (79.4%, 97.1%)
	Month 18	76.8% (54.5%, 89.2%)	92.1% (79.4%, 97.1%)
	Month 24	76.8% (54.5%, 89.2%)	92.1% (79.4%, 97.1%)
	Month 30	76.8% (54.5%, 89.2%)	92.1% (79.4%, 97.1%)
	Month 36	76.8% (54.5%, 89.2%)	92.1% (79.4%, 97.1%)
	Hazard ratio[b] (95% CI)	1.65 (0.481, 5.627)	
	p-value of 2-sided stratified log-rank test	0.4204	
	p-value from Interaction Test[c]	0.9031	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	14 (15.7%)	2 (2.3%)
	Censored	75 (84.3%)	85 (97.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (8.3, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	86.8% (77.4%, 92.5%)	97.7% (91.0%, 99.4%)
	Month 12	82.7% (71.5%, 89.8%)	97.7% (91.0%, 99.4%)
	Month 18	78.7% (64.6%, 87.8%)	97.7% (91.0%, 99.4%)
	Month 24	78.7% (64.6%, 87.8%)	97.7% (91.0%, 99.4%)
	Month 30	78.7% (64.6%, 87.8%)	97.7% (91.0%, 99.4%)
	Month 36	78.7% (64.6%, 87.8%)	97.7% (91.0%, 99.4%)
	Hazard ratio[b] (95% CI)	6.86 (1.557, 30.202)	
	p-value of 2-sided stratified log-rank test	0.0031	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	3 (8.6%)	4 (13.3%)
	Censored	32 (91.4%)	26 (86.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (4.3, NE)	NE (5.6, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	90.9% (74.2%, 97.0%)	84.5% (63.5%, 94.0%)
	Month 12	90.9% (74.2%, 97.0%)	84.5% (63.5%, 94.0%)
	Month 18	90.9% (74.2%, 97.0%)	84.5% (63.5%, 94.0%)
	Month 24	90.9% (74.2%, 97.0%)	84.5% (63.5%, 94.0%)
	Month 30	90.9% (74.2%, 97.0%)	84.5% (63.5%, 94.0%)
	Month 36	90.9% (74.2%, 97.0%)	84.5% (63.5%, 94.0%)
	Hazard ratio[b] (95% CI)	0.78 (0.157, 3.862)	
	p-value of 2-sided stratified log-rank test	0.7593	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	7 (10.8%)	2 (3.1%)
	Censored	58 (89.2%)	62 (96.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (16.7, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Aspartate aminotransferase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	95.1% (85.6%, 98.4%)	98.0% (86.9%, 99.7%)
	Month 12	89.7% (75.8%, 95.8%)	95.8% (84.0%, 98.9%)
	Month 18	84.9% (67.0%, 93.6%)	95.8% (84.0%, 98.9%)
	Month 24	77.9% (54.1%, 90.3%)	95.8% (84.0%, 98.9%)
	Month 30	77.9% (54.1%, 90.3%)	95.8% (84.0%, 98.9%)
	Month 36	77.9% (54.1%, 90.3%)	95.8% (84.0%, 98.9%)
	Hazard ratio[b] (95% CI)	3.31 (0.686, 15.943)	
	p-value of 2-sided stratified log-rank test	0.1139	
	p-value from Interaction Test[c]	0.0837	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	14 (15.7%)	6 (6.9%)
	Censored	75 (84.3%)	81 (93.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (7.3, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	86.2% (76.4%, 92.1%)	95.0% (87.2%, 98.1%)
	Month 12	79.4% (66.8%, 87.7%)	91.6% (82.1%, 96.2%)
	Month 18	79.4% (66.8%, 87.7%)	91.6% (82.1%, 96.2%)
	Month 24	79.4% (66.8%, 87.7%)	91.6% (82.1%, 96.2%)
	Month 30	79.4% (66.8%, 87.7%)	91.6% (82.1%, 96.2%)
	Month 36	79.4% (66.8%, 87.7%)	91.6% (82.1%, 96.2%)
	Hazard ratio[b] (95% CI)	2.26 (0.869, 5.898)	
	p-value of 2-sided stratified log-rank test	0.0856	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	2 (5.7%)	1 (3.3%)
	Censored	33 (94.3%)	29 (96.7%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	8 (12.3%)	3 (4.7%)
	Censored	57 (87.7%)	61 (95.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	21.4 (10.2, NE)	NE (NE, NE)
	50%	NE (21.4, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders
Preferred Term: Hypothyroidism

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	92.8% (81.8%, 97.2%)	96.4% (86.2%, 99.1%)
	Month 12	87.2% (72.8%, 94.2%)	94.1% (82.6%, 98.1%)
	Month 18	83.4% (66.9%, 92.1%)	94.1% (82.6%, 98.1%)
	Month 24	74.1% (47.5%, 88.6%)	94.1% (82.6%, 98.1%)
	Month 30	74.1% (47.5%, 88.6%)	94.1% (82.6%, 98.1%)
	Month 36	74.1% (47.5%, 88.6%)	94.1% (82.6%, 98.1%)
	Hazard ratio[b] (95% CI)	2.68 (0.711, 10.113)	
	p-value of 2-sided stratified log-rank test	0.1293	
	p-value from Interaction Test[c]	0.9609	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_0802_ttae_socpt_dstat.sas, Output: t_3_0802_ttae_socpt_dstat.rtf, Generated on: 03SEP2024 14:20,
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	6 (6.7%)	0
	Censored	83 (93.3%)	87 (100%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	93.1% (85.4%, 96.9%)	100% (100%, 100%)
	Month 12	93.1% (85.4%, 96.9%)	100% (100%, 100%)
	Month 18	93.1% (85.4%, 96.9%)	100% (100%, 100%)
	Month 24	93.1% (85.4%, 96.9%)	100% (100%, 100%)
	Month 30	93.1% (85.4%, 96.9%)	100% (100%, 100%)
	Month 36	93.1% (85.4%, 96.9%)	100% (100%, 100%)
	Hazard ratio[b] (95% CI)	- (-,-)	
	p-value of 2-sided stratified log-rank test	0.0149	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	6 (17.1%)	2 (6.7%)
	Censored	29 (82.9%)	28 (93.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	16.9 (4.1, NE)	NE (6.9, NE)
	50%	NE (16.9, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	88.0% (71.1%, 95.3%)	96.7% (78.6%, 99.5%)
	Month 12	84.2% (65.8%, 93.2%)	92.1% (71.3%, 98.0%)
	Month 18	73.7% (43.9%, 89.3%)	92.1% (71.3%, 98.0%)
	Month 24	73.7% (43.9%, 89.3%)	92.1% (71.3%, 98.0%)
	Month 30	73.7% (43.9%, 89.3%)	92.1% (71.3%, 98.0%)
	Month 36	73.7% (43.9%, 89.3%)	92.1% (71.3%, 98.0%)
	Hazard ratio[b] (95% CI)	2.67 (0.534, 13.319)	
	p-value of 2-sided stratified log-rank test	0.2121	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	6 (9.2%)	4 (6.3%)
	Censored	59 (90.8%)	60 (93.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (15.0, NE)	NE (12.4, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Psychiatric disorders
Preferred Term: Depression

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	95.0% (85.3%, 98.4%)	96.5% (86.5%, 99.1%)
	Month 12	90.7% (78.9%, 96.1%)	96.5% (86.5%, 99.1%)
	Month 18	86.4% (70.2%, 94.1%)	86.3% (64.0%, 95.2%)
	Month 24	86.4% (70.2%, 94.1%)	86.3% (64.0%, 95.2%)
	Month 30	86.4% (70.2%, 94.1%)	86.3% (64.0%, 95.2%)
	Month 36	86.4% (70.2%, 94.1%)	86.3% (64.0%, 95.2%)
	Hazard ratio[b] (95% CI)	1.40 (0.395, 4.984)	
	p-value of 2-sided stratified log-rank test	0.5994	
	p-value from Interaction Test[c]	0.8033	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	3 (3.4%)	6 (6.9%)
	Censored	86 (96.6%)	81 (93.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (19.8, NE)	NE (17.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	97.6% (90.9%, 99.4%)	95.3% (87.9%, 98.2%)
	Month 12	97.6% (90.9%, 99.4%)	93.6% (85.0%, 97.3%)
	Month 18	97.6% (90.9%, 99.4%)	85.1% (58.1%, 95.3%)
	Month 24	92.8% (73.5%, 98.2%)	85.1% (58.1%, 95.3%)
	Month 30	92.8% (73.5%, 98.2%)	85.1% (58.1%, 95.3%)
	Month 36	92.8% (73.5%, 98.2%)	85.1% (58.1%, 95.3%)
	Hazard ratio[b] (95% CI)	0.42 (0.103, 1.683)	
	p-value of 2-sided stratified log-rank test	0.2048	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	0	0
	Censored	35 (100%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	2 (3.1%)	9 (14.1%)
	Censored	63 (96.9%)	55 (85.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (5.6, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Nervous system disorders
Preferred Term: Paraesthesia

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	96.8% (88.0%, 99.2%)	85.3% (73.6%, 92.1%)
	Month 12	96.8% (88.0%, 99.2%)	85.3% (73.6%, 92.1%)
	Month 18	96.8% (88.0%, 99.2%)	85.3% (73.6%, 92.1%)
	Month 24	96.8% (88.0%, 99.2%)	85.3% (73.6%, 92.1%)
	Month 30	96.8% (88.0%, 99.2%)	85.3% (73.6%, 92.1%)
	Month 36	96.8% (88.0%, 99.2%)	85.3% (73.6%, 92.1%)
	Hazard ratio[b] (95% CI)	0.22 (0.047, 0.998)	
	p-value of 2-sided stratified log-rank test	0.0306	
	p-value from Interaction Test[c]	0.7421	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Pneumonia

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	5 (5.6%)	0
	Censored	84 (94.4%)	87 (100%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (24.4, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Pneumonia

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	96.4% (89.3%, 98.8%)	100% (100%, 100%)
	Month 12	96.4% (89.3%, 98.8%)	100% (100%, 100%)
	Month 18	93.1% (80.3%, 97.7%)	100% (100%, 100%)
	Month 24	93.1% (80.3%, 97.7%)	100% (100%, 100%)
	Month 30	87.6% (67.6%, 95.6%)	100% (100%, 100%)
	Month 36	87.6% (67.6%, 95.6%)	100% (100%, 100%)
	Hazard ratio[b] (95% CI)	- (-,-)	
	p-value of 2-sided stratified log-rank test	0.0409	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Pneumonia

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	1 (2.9%)	2 (6.7%)
	Censored	34 (97.1%)	28 (93.3%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations
Preferred Term: Pneumonia

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	4 (6.2%)	0
	Censored	61 (93.8%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypocalcaemia

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	4 (4.5%)	1 (1.1%)
	Censored	85 (95.5%)	86 (98.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypocalcaemia

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	95.5% (88.5%, 98.3%)	98.9% (92.1%, 99.8%)
	Month 12	95.5% (88.5%, 98.3%)	98.9% (92.1%, 99.8%)
	Month 18	95.5% (88.5%, 98.3%)	98.9% (92.1%, 99.8%)
	Month 24	95.5% (88.5%, 98.3%)	98.9% (92.1%, 99.8%)
	Month 30	95.5% (88.5%, 98.3%)	98.9% (92.1%, 99.8%)
	Month 36	95.5% (88.5%, 98.3%)	98.9% (92.1%, 99.8%)
	Hazard ratio[b] (95% CI)	3.97 (0.444, 35.536)	
	p-value of 2-sided stratified log-rank test	0.1829	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypocalcaemia

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	2 (5.7%)	0
	Censored	33 (94.3%)	30 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Metabolism and nutrition disorders
Preferred Term: Hypocalcaemia

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	3 (4.6%)	1 (1.6%)
	Censored	62 (95.4%)	63 (98.4%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Pollakiuria

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	3 (3.4%)	1 (1.1%)
	Censored	86 (96.6%)	86 (98.9%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Pollakiuria

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	5 (14.3%)	0
	Censored	30 (85.7%)	30 (100%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	28.9 (8.8, NE)	NE (NE, NE)
	50%	NE (28.9, NE)	NE (NE, NE)
	75%	NE (28.9, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Pollakiuria

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	94.3% (79.0%, 98.5%)	100% (100%, 100%)
	Month 12	85.7% (65.4%, 94.5%)	100% (100%, 100%)
	Month 18	85.7% (65.4%, 94.5%)	100% (100%, 100%)
	Month 24	85.7% (65.4%, 94.5%)	100% (100%, 100%)
	Month 30	64.3% (18.9%, 88.9%)	100% (100%, 100%)
	Month 36	64.3% (18.9%, 88.9%)	100% (100%, 100%)
	Hazard ratio[b] (95% CI)	- (-,-)	
	p-value of 2-sided stratified log-rank test	0.0204	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.0802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Renal and urinary disorders
Preferred Term: Pollakiuria

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	2 (3.1%)	0
	Censored	63 (96.9%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
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Table 3.1002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	43 (44.8%)	27 (32.9%)
	Censored	53 (55.2%)	55 (67.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	2.8 (1.4, 5.6)	2.8 (1.4, 12.8)
	50%	14.1 (9.6, NE)	NE (12.8, NE)
	75%	NE (17.5, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

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Table 3.1002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	65.3% (54.5%, 74.1%)	70.4% (58.8%, 79.3%)
	Month 12	54.2% (41.9%, 64.9%)	66.8% (54.7%, 76.4%)
	Month 18	39.7% (24.9%, 54.1%)	58.9% (43.5%, 71.4%)
	Month 24	39.7% (24.9%, 54.1%)	58.9% (43.5%, 71.4%)
	Month 30	34.0% (18.5%, 50.2%)	58.9% (43.5%, 71.4%)
	Month 36	34.0% (18.5%, 50.2%)	58.9% (43.5%, 71.4%)
	Hazard ratio[b] (95% CI)	1.51 (0.916, 2.480)	
	p-value of 2-sided stratified log-rank test	0.1059	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

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Table 3.1002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	43 (46.2%)	37 (37.4%)
	Censored	50 (53.8%)	62 (62.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	1.4 (0.5, 2.1)	2.4 (1.7, 4.2)
	50%	12.7 (3.0, NE)	NE (9.9, NE)
	75%	NE (23.8, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

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Table 3.1002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	55.3% (44.3%, 65.0%)	64.4% (53.8%, 73.1%)
	Month 12	53.3% (42.0%, 63.3%)	55.7% (42.1%, 67.3%)
	Month 18	49.2% (36.1%, 61.0%)	55.7% (42.1%, 67.3%)
	Month 24	36.9% (15.6%, 58.6%)	55.7% (42.1%, 67.3%)
	Month 30	36.9% (15.6%, 58.6%)	55.7% (42.1%, 67.3%)
	Month 36	36.9% (15.6%, 58.6%)	55.7% (42.1%, 67.3%)
	Hazard ratio[b] (95% CI)	1.35 (0.869, 2.112)	
	p-value of 2-sided stratified log-rank test	0.1777	
	p-value from Interaction Test[c]	0.8819	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

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Table 3.1002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	17 (17.7%)	6 (7.3%)
	Censored	79 (82.3%)	76 (92.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (7.6, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

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Table 3.1002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	85.2% (75.8%, 91.1%)	95.7% (87.3%, 98.6%)
	Month 12	76.2% (63.3%, 85.1%)	92.3% (82.4%, 96.7%)
	Month 18	76.2% (63.3%, 85.1%)	89.4% (77.1%, 95.3%)
	Month 24	76.2% (63.3%, 85.1%)	89.4% (77.1%, 95.3%)
	Month 30	76.2% (63.3%, 85.1%)	89.4% (77.1%, 95.3%)
	Month 36	76.2% (63.3%, 85.1%)	89.4% (77.1%, 95.3%)
	Hazard ratio[b] (95% CI)	2.65 (1.041, 6.730)	
	p-value of 2-sided stratified log-rank test	0.0337	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

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Table 3.1002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	17 (18.3%)	8 (8.1%)
	Censored	76 (81.7%)	91 (91.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	21.4 (6.9, NE)	NE (19.4, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1002_ttae_soc_age.sas, Output: t_3_1002_ttae_soc_age.rtf, Generated on: 30AUG2024 12:19,

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Table 3.1002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	87.5% (78.0%, 93.1%)	93.6% (86.2%, 97.1%)
	Month 12	79.9% (68.6%, 87.5%)	92.1% (83.9%, 96.2%)
	Month 18	77.3% (65.0%, 85.7%)	92.1% (83.9%, 96.2%)
	Month 24	71.4% (53.8%, 83.2%)	84.4% (61.0%, 94.3%)
	Month 30	71.4% (53.8%, 83.2%)	84.4% (61.0%, 94.3%)
	Month 36	71.4% (53.8%, 83.2%)	84.4% (61.0%, 94.3%)
	Hazard ratio[b] (95% CI)	2.26 (0.971, 5.239)	
	p-value of 2-sided stratified log-rank test	0.0517	
	p-value from Interaction Test[c]	0.7495	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1002_ttae_soc_age.sas, Output: t_3_1002_ttae_soc_age.rtf, Generated on: 30AUG2024 12:19,

Data Cutoff Date: 22SEP2023

Table 3.1002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	17 (17.7%)	7 (8.5%)
	Censored	79 (82.3%)	75 (91.5%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	43.0 (5.6, NE)	NE (16.0, NE)
	50%	43.0 (NE, NE)	NE (NE, NE)
	75%	43.0 (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1002_ttae_soc_age.sas, Output: t_3_1002_ttae_soc_age.rtf, Generated on: 30AUG2024 12:19,

Data Cutoff Date: 22SEP2023

Table 3.1002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	83.5% (74.1%, 89.7%)	94.9% (86.9%, 98.0%)
	Month 12	81.1% (70.3%, 88.2%)	90.8% (80.2%, 95.9%)
	Month 18	81.1% (70.3%, 88.2%)	87.2% (73.2%, 94.2%)
	Month 24	81.1% (70.3%, 88.2%)	87.2% (73.2%, 94.2%)
	Month 30	81.1% (70.3%, 88.2%)	87.2% (73.2%, 94.2%)
	Month 36	81.1% (70.3%, 88.2%)	87.2% (73.2%, 94.2%)
	Hazard ratio[b] (95% CI)	2.20 (0.908, 5.348)	
	p-value of 2-sided stratified log-rank test	0.0733	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1002_ttae_soc_age.sas, Output: t_3_1002_ttae_soc_age.rtf, Generated on: 30AUG2024 12:19,

Data Cutoff Date: 22SEP2023

Table 3.1002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	14 (15.1%)	9 (9.1%)
	Censored	79 (84.9%)	90 (90.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	31.8 (23.5, NE)	NE (NE, NE)
	50%	NE (34.1, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1002_ttae_soc_age.sas, Output: t_3_1002_ttae_soc_age.rtf, Generated on: 30AUG2024 12:19,

Data Cutoff Date: 22SEP2023

Table 3.1002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	88.8% (80.2%, 93.8%)	90.8% (83.1%, 95.1%)
	Month 12	87.4% (78.3%, 92.8%)	90.8% (83.1%, 95.1%)
	Month 18	87.4% (78.3%, 92.8%)	90.8% (83.1%, 95.1%)
	Month 24	81.6% (64.4%, 91.0%)	90.8% (83.1%, 95.1%)
	Month 30	81.6% (64.4%, 91.0%)	90.8% (83.1%, 95.1%)
	Month 36	61.8% (30.6%, 82.2%)	90.8% (83.1%, 95.1%)
	Hazard ratio[b] (95% CI)	1.55 (0.666, 3.621)	
	p-value of 2-sided stratified log-rank test	0.3039	
	p-value from Interaction Test[c]	0.5874	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1002_ttae_soc_age.sas, Output: t_3_1002_ttae_soc_age.rtf, Generated on: 30AUG2024 12:19,

Data Cutoff Date: 22SEP2023

Table 3.1102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	65 (48.9%)	49 (36.0%)
	Censored	68 (51.1%)	87 (64.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	1.5 (0.8, 2.1)	2.2 (1.5, 4.2)
	50%	13.8 (5.6, 27.5)	NE (11.1, NE)
	75%	NE (23.8, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1102_ttae_soc_reg.sas, Output: t_3_1102_ttae_soc_reg.rtf, Generated on: 30AUG2024 12:22,

Data Cutoff Date: 22SEP2023

Table 3.1102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	57.2% (48.1%, 65.3%)	65.8% (56.9%, 73.4%)
	Month 12	53.5% (44.0%, 62.0%)	58.0% (47.3%, 67.2%)
	Month 18	41.7% (29.9%, 53.0%)	58.0% (47.3%, 67.2%)
	Month 24	37.1% (23.9%, 50.2%)	58.0% (47.3%, 67.2%)
	Month 30	32.4% (18.7%, 46.9%)	58.0% (47.3%, 67.2%)
	Month 36	32.4% (18.7%, 46.9%)	58.0% (47.3%, 67.2%)
	Hazard ratio[b] (95% CI)	1.46 (1.005, 2.135)	
	p-value of 2-sided stratified log-rank test	0.0459	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1102_ttae_soc_reg.sas, Output: t_3_1102_ttae_soc_reg.rtf, Generated on: 30AUG2024 12:22,

Data Cutoff Date: 22SEP2023

Table 3.1102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	21 (37.5%)	15 (33.3%)
	Censored	35 (62.5%)	30 (66.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	3.0 (1.2, 8.2)	3.5 (1.3, 14.2)
	50%	11.6 (8.2, NE)	NE (12.8, NE)
	75%	NE (11.6, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1102_ttae_soc_reg.sas, Output: t_3_1102_ttae_soc_reg.rtf, Generated on: 30AUG2024 12:22,

Data Cutoff Date: 22SEP2023

Table 3.1102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	68.1% (53.6%, 78.9%)	70.8% (55.0%, 81.9%)
	Month 12	46.6% (24.5%, 66.1%)	70.8% (55.0%, 81.9%)
	Month 18	46.6% (24.5%, 66.1%)	52.4% (26.5%, 73.1%)
	Month 24	46.6% (24.5%, 66.1%)	52.4% (26.5%, 73.1%)
	Month 30	46.6% (24.5%, 66.1%)	52.4% (26.5%, 73.1%)
	Month 36	NE (NE, NE)	52.4% (26.5%, 73.1%)
	Hazard ratio[b] (95% CI)	1.27 (0.636, 2.526)	
	p-value of 2-sided stratified log-rank test	0.4933	
	p-value from Interaction Test[c]	0.6513	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1102_ttae_soc_reg.sas, Output: t_3_1102_ttae_soc_reg.rtf, Generated on: 30AUG2024 12:22,

Data Cutoff Date: 22SEP2023

Table 3.1102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	22 (16.5%)	12 (8.8%)
	Censored	111 (83.5%)	124 (91.2%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (10.2, NE)	NE (19.4, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1102_ttae_soc_reg.sas, Output: t_3_1102_ttae_soc_reg.rtf, Generated on: 30AUG2024 12:22,

Data Cutoff Date: 22SEP2023

Table 3.1102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	86.6% (79.0%, 91.6%)	93.4% (87.2%, 96.7%)
	Month 12	81.3% (72.1%, 87.7%)	91.2% (84.2%, 95.2%)
	Month 18	79.5% (69.7%, 86.5%)	88.8% (79.6%, 94.0%)
	Month 24	75.1% (61.4%, 84.6%)	84.6% (70.5%, 92.3%)
	Month 30	75.1% (61.4%, 84.6%)	84.6% (70.5%, 92.3%)
	Month 36	75.1% (61.4%, 84.6%)	84.6% (70.5%, 92.3%)
	Hazard ratio[b] (95% CI)	1.88 (0.930, 3.813)	
	p-value of 2-sided stratified log-rank test	0.0732	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1102_ttae_soc_reg.sas, Output: t_3_1102_ttae_soc_reg.rtf, Generated on: 30AUG2024 12:22,

Data Cutoff Date: 22SEP2023

Table 3.1102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	12 (21.4%)	2 (4.4%)
	Censored	44 (78.6%)	43 (95.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	7.6 (4.4, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1102_ttae_soc_reg.sas, Output: t_3_1102_ttae_soc_reg.rtf, Generated on: 30AUG2024 12:22,

Data Cutoff Date: 22SEP2023

Table 3.1102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	85.5% (71.8%, 92.8%)	97.8% (85.3%, 99.7%)
	Month 12	69.0% (50.7%, 81.7%)	94.8% (80.5%, 98.7%)
	Month 18	69.0% (50.7%, 81.7%)	94.8% (80.5%, 98.7%)
	Month 24	69.0% (50.7%, 81.7%)	94.8% (80.5%, 98.7%)
	Month 30	69.0% (50.7%, 81.7%)	94.8% (80.5%, 98.7%)
	Month 36	69.0% (50.7%, 81.7%)	94.8% (80.5%, 98.7%)
	Hazard ratio[b] (95% CI)	6.13 (1.357, 27.704)	
	p-value of 2-sided stratified log-rank test	0.0074	
	p-value from Interaction Test[c]	0.1539	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1102_ttae_soc_reg.sas, Output: t_3_1102_ttae_soc_reg.rtf, Generated on: 30AUG2024 12:22,

Data Cutoff Date: 22SEP2023

Table 3.1102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	24 (18.0%)	11 (8.1%)
	Censored	109 (82.0%)	125 (91.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	34.1 (23.5, NE)	NE (NE, NE)
	50%	43.0 (NE, NE)	NE (NE, NE)
	75%	43.0 (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1102_ttae_soc_reg.sas, Output: t_3_1102_ttae_soc_reg.rtf, Generated on: 30AUG2024 12:22,

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Table 3.1102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	85.0% (77.5%, 90.2%)	93.2% (87.3%, 96.4%)
	Month 12	83.5% (75.5%, 89.2%)	92.1% (85.7%, 95.7%)
	Month 18	83.5% (75.5%, 89.2%)	89.0% (78.7%, 94.5%)
	Month 24	80.1% (68.7%, 87.6%)	89.0% (78.7%, 94.5%)
	Month 30	80.1% (68.7%, 87.6%)	89.0% (78.7%, 94.5%)
	Month 36	69.5% (50.3%, 82.5%)	89.0% (78.7%, 94.5%)
	Hazard ratio[b] (95% CI)	2.11 (1.031, 4.333)	
	p-value of 2-sided stratified log-rank test	0.0365	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1102_ttae_soc_reg.sas, Output: t_3_1102_ttae_soc_reg.rtf, Generated on: 30AUG2024 12:22,

Data Cutoff Date: 22SEP2023

Table 3.1102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	7 (12.5%)	5 (11.1%)
	Censored	49 (87.5%)	40 (88.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (6.0, NE)	NE (9.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1102_ttae_soc_reg.sas, Output: t_3_1102_ttae_soc_reg.rtf, Generated on: 30AUG2024 12:22,

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Table 3.1102 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	89.1% (77.3%, 95.0%)	91.1% (78.0%, 96.6%)
	Month 12	86.6% (73.6%, 93.4%)	86.8% (69.8%, 94.6%)
	Month 18	86.6% (73.6%, 93.4%)	86.8% (69.8%, 94.6%)
	Month 24	86.6% (73.6%, 93.4%)	86.8% (69.8%, 94.6%)
	Month 30	86.6% (73.6%, 93.4%)	86.8% (69.8%, 94.6%)
	Month 36	86.6% (73.6%, 93.4%)	86.8% (69.8%, 94.6%)
	Hazard ratio[b] (95% CI)	1.20 (0.379, 3.816)	
	p-value of 2-sided stratified log-rank test	0.7534	
	p-value from Interaction Test[c]	0.4188	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1102_ttae_soc_reg.sas, Output: t_3_1102_ttae_soc_reg.rtf, Generated on: 30AUG2024 12:22,

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Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	40 (44.9%)	29 (33.3%)
	Censored	49 (55.1%)	58 (66.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	1.6 (0.7, 3.5)	2.1 (1.4, 11.1)
	50%	16.3 (5.6, 27.5)	NE (11.1, NE)
	75%	27.5 (23.8, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

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Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	58.4% (46.9%, 68.3%)	67.9% (56.8%, 76.8%)
	Month 12	56.6% (44.9%, 66.7%)	63.4% (49.3%, 74.5%)
	Month 18	43.7% (25.5%, 60.5%)	57.0% (39.2%, 71.4%)
	Month 24	34.9% (15.5%, 55.3%)	57.0% (39.2%, 71.4%)
	Month 30	23.3% (5.5%, 48.1%)	57.0% (39.2%, 71.4%)
	Month 36	NE (NE, NE)	57.0% (39.2%, 71.4%)
	Hazard ratio[b] (95% CI)	1.45 (0.898, 2.350)	
	p-value of 2-sided stratified log-rank test	0.1248	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

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Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	19 (54.3%)	10 (33.3%)
	Censored	16 (45.7%)	20 (66.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	1.5 (0.6, 2.8)	4.2 (1.4, NE)
	50%	9.6 (1.9, NE)	NE (9.9, NE)
	75%	14.1 (12.7, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

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Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	55.4% (37.2%, 70.3%)	72.1% (51.8%, 85.0%)
	Month 12	47.2% (28.8%, 63.5%)	66.6% (44.7%, 81.4%)
	Month 18	NE (NE, NE)	60.5% (37.6%, 77.2%)
	Month 24	NE (NE, NE)	60.5% (37.6%, 77.2%)
	Month 30	NE (NE, NE)	60.5% (37.6%, 77.2%)
	Month 36	NE (NE, NE)	60.5% (37.6%, 77.2%)
	Hazard ratio[b] (95% CI)	2.05 (0.943, 4.476)	
	p-value of 2-sided stratified log-rank test	0.0642	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

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Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	27 (41.5%)	25 (39.1%)
	Censored	38 (58.5%)	39 (60.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	2.1 (0.6, 6.1)	2.4 (1.4, 5.6)
	50%	17.5 (6.1, NE)	NE (6.4, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

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Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Respiratory, thoracic and mediastinal disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	65.3% (52.1%, 75.6%)	63.7% (50.2%, 74.5%)
	Month 12	53.7% (38.5%, 66.7%)	56.1% (41.6%, 68.3%)
	Month 18	49.6% (33.6%, 63.6%)	56.1% (41.6%, 68.3%)
	Month 24	49.6% (33.6%, 63.6%)	56.1% (41.6%, 68.3%)
	Month 30	49.6% (33.6%, 63.6%)	56.1% (41.6%, 68.3%)
	Month 36	49.6% (33.6%, 63.6%)	NE (NE, NE)
	Hazard ratio[b] (95% CI)	1.04 (0.600, 1.818)	
	p-value of 2-sided stratified log-rank test	0.8779	
	p-value from Interaction Test[c]	0.2691	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

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Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	17 (19.1%)	7 (8.0%)
	Censored	72 (80.9%)	80 (92.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (5.5, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

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Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	83.6% (73.3%, 90.2%)	93.8% (85.8%, 97.4%)
	Month 12	75.3% (62.3%, 84.3%)	90.5% (80.9%, 95.4%)
	Month 18	75.3% (62.3%, 84.3%)	90.5% (80.9%, 95.4%)
	Month 24	75.3% (62.3%, 84.3%)	90.5% (80.9%, 95.4%)
	Month 30	75.3% (62.3%, 84.3%)	90.5% (80.9%, 95.4%)
	Month 36	75.3% (62.3%, 84.3%)	90.5% (80.9%, 95.4%)
	Hazard ratio[b] (95% CI)	2.36 (0.979, 5.702)	
	p-value of 2-sided stratified log-rank test	0.0485	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

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Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	4 (11.4%)	3 (10.0%)
	Censored	31 (88.6%)	27 (90.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (3.8, NE)	NE (12.5, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

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Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	87.8% (70.6%, 95.2%)	96.2% (75.7%, 99.4%)
	Month 12	87.8% (70.6%, 95.2%)	96.2% (75.7%, 99.4%)
	Month 18	87.8% (70.6%, 95.2%)	89.3% (61.7%, 97.4%)
	Month 24	87.8% (70.6%, 95.2%)	81.2% (50.3%, 93.9%)
	Month 30	87.8% (70.6%, 95.2%)	81.2% (50.3%, 93.9%)
	Month 36	87.8% (70.6%, 95.2%)	81.2% (50.3%, 93.9%)
	Hazard ratio[b] (95% CI)	1.33 (0.290, 6.069)	
	p-value of 2-sided stratified log-rank test	0.7139	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

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Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	13 (20.0%)	4 (6.3%)
	Censored	52 (80.0%)	60 (93.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	12.5 (6.4, NE)	NE (NE, NE)
	50%	NE (21.4, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

Data Cutoff Date: 22SEP2023

Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Endocrine disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	89.1% (77.3%, 95.0%)	94.8% (84.6%, 98.3%)
	Month 12	76.3% (60.5%, 86.4%)	92.5% (81.1%, 97.2%)
	Month 18	72.5% (55.4%, 83.9%)	92.5% (81.1%, 97.2%)
	Month 24	63.4% (39.3%, 80.1%)	92.5% (81.1%, 97.2%)
	Month 30	63.4% (39.3%, 80.1%)	92.5% (81.1%, 97.2%)
	Month 36	63.4% (39.3%, 80.1%)	92.5% (81.1%, 97.2%)
	Hazard ratio[b] (95% CI)	3.44 (1.122, 10.559)	
	p-value of 2-sided stratified log-rank test	0.0213	
	p-value from Interaction Test[c]	0.6086	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

Data Cutoff Date: 22SEP2023

Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	9 (10.1%)	8 (9.2%)
	Censored	80 (89.9%)	79 (90.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (31.8, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

Data Cutoff Date: 22SEP2023

Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	92.0% (84.0%, 96.1%)	90.5% (81.9%, 95.1%)
	Month 12	89.3% (78.7%, 94.8%)	90.5% (81.9%, 95.1%)
	Month 18	89.3% (78.7%, 94.8%)	90.5% (81.9%, 95.1%)
	Month 24	89.3% (78.7%, 94.8%)	90.5% (81.9%, 95.1%)
	Month 30	89.3% (78.7%, 94.8%)	90.5% (81.9%, 95.1%)
	Month 36	81.2% (57.2%, 92.5%)	90.5% (81.9%, 95.1%)
	Hazard ratio[b] (95% CI)	0.98 (0.376, 2.557)	
	p-value of 2-sided stratified log-rank test	0.9673	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

Data Cutoff Date: 22SEP2023

Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	9 (25.7%)	1 (3.3%)
	Censored	26 (74.3%)	29 (96.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	34.1 (1.7, NE)	NE (16.0, NE)
	50%	43.0 (34.1, NE)	NE (NE, NE)
	75%	43.0 (34.1, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

Data Cutoff Date: 22SEP2023

Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	78.6% (60.1%, 89.2%)	100% (100%, 100%)
	Month 12	78.6% (60.1%, 89.2%)	100% (100%, 100%)
	Month 18	78.6% (60.1%, 89.2%)	91.7% (53.9%, 98.8%)
	Month 24	78.6% (60.1%, 89.2%)	91.7% (53.9%, 98.8%)
	Month 30	78.6% (60.1%, 89.2%)	91.7% (53.9%, 98.8%)
	Month 36	52.4% (10.0%, 83.4%)	91.7% (53.9%, 98.8%)
	Hazard ratio[b] (95% CI)	8.69 (1.097, 68.794)	
	p-value of 2-sided stratified log-rank test	0.0137	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

Data Cutoff Date: 22SEP2023

Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	13 (20.0%)	7 (10.9%)
	Censored	52 (80.0%)	57 (89.1%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	23.5 (3.4, NE)	NE (9.7, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

Data Cutoff Date: 22SEP2023

Table 3.1202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Cardiac disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	82.1% (69.9%, 89.7%)	92.1% (82.0%, 96.6%)
	Month 12	80.0% (67.4%, 88.2%)	86.4% (72.4%, 93.6%)
	Month 18	80.0% (67.4%, 88.2%)	86.4% (72.4%, 93.6%)
	Month 24	73.3% (54.0%, 85.6%)	86.4% (72.4%, 93.6%)
	Month 30	73.3% (54.0%, 85.6%)	86.4% (72.4%, 93.6%)
	Month 36	73.3% (54.0%, 85.6%)	86.4% (72.4%, 93.6%)
	Hazard ratio[b] (95% CI)	1.87 (0.746, 4.693)	
	p-value of 2-sided stratified log-rank test	0.1745	
	p-value from Interaction Test[c]	0.1665	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_1202_ttae_soc_dstat.sas, Output: t_3_1202_ttae_soc_dstat.rtf, Generated on: 30AUG2024 12:24,

Data Cutoff Date: 22SEP2023

Table 3.2202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	16 (16.7%)	5 (6.1%)
	Censored	80 (83.3%)	77 (93.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (9.0, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_2202_ttsae_soc_age.sas, Output: t_3_2202_ttsae_soc_age.rtf, Generated on: 30AUG2024 12:33,

Data Cutoff Date: 22SEP2023

Table 3.2202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	87.0% (78.3%, 92.4%)	95.8% (87.5%, 98.7%)
	Month 12	79.2% (67.5%, 87.2%)	93.7% (83.5%, 97.6%)
	Month 18	79.2% (67.5%, 87.2%)	90.7% (78.1%, 96.3%)
	Month 24	79.2% (67.5%, 87.2%)	90.7% (78.1%, 96.3%)
	Month 30	79.2% (67.5%, 87.2%)	90.7% (78.1%, 96.3%)
	Month 36	79.2% (67.5%, 87.2%)	90.7% (78.1%, 96.3%)
	Hazard ratio[b] (95% CI)	2.82 (1.031, 7.727)	
	p-value of 2-sided stratified log-rank test	0.0349	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_2202_ttsae_soc_age.sas, Output: t_3_2202_ttsae_soc_age.rtf, Generated on: 30AUG2024 12:33,

Data Cutoff Date: 22SEP2023

Table 3.2202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	6 (6.5%)	2 (2.0%)
	Censored	87 (93.5%)	97 (98.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (19.1, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_2202_ttsae_soc_age.sas, Output: t_3_2202_ttsae_soc_age.rtf, Generated on: 30AUG2024 12:33,

Data Cutoff Date: 22SEP2023

Table 3.2202 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	96.2% (88.6%, 98.8%)	97.7% (91.0%, 99.4%)
	Month 12	93.1% (84.0%, 97.1%)	97.7% (91.0%, 99.4%)
	Month 18	93.1% (84.0%, 97.1%)	97.7% (91.0%, 99.4%)
	Month 24	88.6% (73.2%, 95.5%)	97.7% (91.0%, 99.4%)
	Month 30	88.6% (73.2%, 95.5%)	97.7% (91.0%, 99.4%)
	Month 36	88.6% (73.2%, 95.5%)	97.7% (91.0%, 99.4%)
	Hazard ratio[b] (95% CI)	6.21 (0.741, 52.097)	
	p-value of 2-sided stratified log-rank test	0.0550	
	p-value from Interaction Test[c]	0.9310	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_2202_ttsae_soc_age.sas, Output: t_3_2202_ttsae_soc_age.rtf, Generated on: 30AUG2024 12:33,

Data Cutoff Date: 22SEP2023

Table 3.2302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	18 (13.5%)	5 (3.7%)
	Censored	115 (86.5%)	131 (96.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (19.1, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_2302_ttsae_soc_reg.sas, Output: t_3_2302_ttsae_soc_reg.rtf, Generated on: 30AUG2024 12:36,

Data Cutoff Date: 22SEP2023

Table 3.2302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	90.6% (84.0%, 94.6%)	95.7% (89.9%, 98.2%)
	Month 12	84.8% (76.4%, 90.4%)	95.7% (89.9%, 98.2%)
	Month 18	84.8% (76.4%, 90.4%)	95.7% (89.9%, 98.2%)
	Month 24	82.0% (71.4%, 88.9%)	95.7% (89.9%, 98.2%)
	Month 30	82.0% (71.4%, 88.9%)	95.7% (89.9%, 98.2%)
	Month 36	82.0% (71.4%, 88.9%)	95.7% (89.9%, 98.2%)
	Hazard ratio[b] (95% CI)	4.45 (1.503, 13.187)	
	p-value of 2-sided stratified log-rank test	0.0032	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_2302_ttsae_soc_reg.sas, Output: t_3_2302_ttsae_soc_reg.rtf, Generated on: 30AUG2024 12:36,

Data Cutoff Date: 22SEP2023

Table 3.2302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	4 (7.1%)	2 (4.4%)
	Censored	52 (92.9%)	43 (95.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (10.3, NE)	NE (9.9, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_2302_ttsae_soc_reg.sas, Output: t_3_2302_ttsae_soc_reg.rtf, Generated on: 30AUG2024 12:36,

Data Cutoff Date: 22SEP2023

Table 3.2302 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	93.5% (80.9%, 97.9%)	100% (100%, 100%)
	Month 12	89.0% (71.6%, 96.0%)	95.5% (71.9%, 99.3%)
	Month 18	89.0% (71.6%, 96.0%)	89.1% (62.2%, 97.2%)
	Month 24	89.0% (71.6%, 96.0%)	89.1% (62.2%, 97.2%)
	Month 30	89.0% (71.6%, 96.0%)	89.1% (62.2%, 97.2%)
	Month 36	89.0% (71.6%, 96.0%)	89.1% (62.2%, 97.2%)
	Hazard ratio[b] (95% CI)	2.16 (0.381, 12.267)	
	p-value of 2-sided stratified log-rank test	0.3743	
	p-value from Interaction Test[c]	0.6187	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_2302_ttsae_soc_reg.sas, Output: t_3_2302_ttsae_soc_reg.rtf, Generated on: 30AUG2024 12:36,

Data Cutoff Date: 22SEP2023

Table 3.2402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	10 (11.2%)	2 (2.3%)
	Censored	79 (88.8%)	85 (97.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (19.1, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_2402_ttsae_soc_dstat.sas, Output: t_3_2402_ttsae_soc_dstat.rtf, Generated on: 30AUG2024 12:37,

Data Cutoff Date: 22SEP2023

Table 3.2402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	91.8% (83.6%, 96.0%)	98.8% (91.6%, 99.8%)
	Month 12	87.2% (75.7%, 93.4%)	96.0% (83.6%, 99.1%)
	Month 18	87.2% (75.7%, 93.4%)	96.0% (83.6%, 99.1%)
	Month 24	83.0% (67.9%, 91.4%)	96.0% (83.6%, 99.1%)
	Month 30	83.0% (67.9%, 91.4%)	96.0% (83.6%, 99.1%)
	Month 36	83.0% (67.9%, 91.4%)	96.0% (83.6%, 99.1%)
	Hazard ratio[b] (95% CI)	4.45 (0.969, 20.445)	
	p-value of 2-sided stratified log-rank test	0.0360	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_2402_ttsae_soc_dstat.sas, Output: t_3_2402_ttsae_soc_dstat.rtf, Generated on: 30AUG2024 12:37,
Data Cutoff Date: 22SEP2023

Table 3.2402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	2 (5.7%)	1 (3.3%)
	Censored	33 (94.3%)	29 (96.7%)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_2402_ttsae_soc_dstat.sas, Output: t_3_2402_ttsae_soc_dstat.rtf, Generated on: 30AUG2024 12:37,

Data Cutoff Date: 22SEP2023

Table 3.2402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	10 (15.4%)	4 (6.3%)
	Censored	55 (84.6%)	60 (93.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (6.8, NE)	NE (12.5, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_2402_ttsae_soc_dstat.sas, Output: t_3_2402_ttsae_soc_dstat.rtf, Generated on: 30AUG2024 12:37,

Data Cutoff Date: 22SEP2023

Table 3.2402 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Serious Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	89.6% (78.2%, 95.2%)	94.8% (84.7%, 98.3%)
	Month 12	79.5% (64.6%, 88.7%)	94.8% (84.7%, 98.3%)
	Month 18	79.5% (64.6%, 88.7%)	90.1% (72.5%, 96.7%)
	Month 24	79.5% (64.6%, 88.7%)	90.1% (72.5%, 96.7%)
	Month 30	79.5% (64.6%, 88.7%)	90.1% (72.5%, 96.7%)
	Month 36	79.5% (64.6%, 88.7%)	90.1% (72.5%, 96.7%)
	Hazard ratio[b] (95% CI)	2.62 (0.822, 8.358)	
	p-value of 2-sided stratified log-rank test	0.0911	
	p-value from Interaction Test[c]	0.7381	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_2402_ttsae_soc_dstat.sas, Output: t_3_2402_ttsae_soc_dstat.rtf, Generated on: 30AUG2024 12:37,
Data Cutoff Date: 22SEP2023

Table 3.3402 Summary of Kaplan Meier Analysis of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Amylase increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	4 (4.2%)	1 (1.2%)
	Censored	92 (95.8%)	81 (98.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (34.7, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_3402_ttae3_socpt_age.sas, Output: t_3_3402_ttae3_socpt_age.rtf, Generated on: 03SEP2024 11:45,
Data Cutoff Date: 22SEP2023

Table 3.3402 Summary of Kaplan Meier Analysis of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Amylase increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	98.9% (92.8%, 99.9%)	98.8% (91.6%, 99.8%)
	Month 12	95.9% (87.7%, 98.7%)	98.8% (91.6%, 99.8%)
	Month 18	95.9% (87.7%, 98.7%)	98.8% (91.6%, 99.8%)
	Month 24	95.9% (87.7%, 98.7%)	98.8% (91.6%, 99.8%)
	Month 30	95.9% (87.7%, 98.7%)	98.8% (91.6%, 99.8%)
	Month 36	87.2% (57.1%, 96.7%)	98.8% (91.6%, 99.8%)
	Hazard ratio[b] (95% CI)	3.26 (0.362, 29.323)	
	p-value of 2-sided stratified log-rank test	0.2647	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_3402_ttae3_socpt_age.sas, Output: t_3_3402_ttae3_socpt_age.rtf, Generated on: 03SEP2024 11:45,
Data Cutoff Date: 22SEP2023

Table 3.3402 Summary of Kaplan Meier Analysis of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Amylase increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	5 (5.4%)	0
	Censored	88 (94.6%)	99 (100%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	40.2 (23.6, NE)	NE (NE, NE)
	50%	40.2 (NE, NE)	NE (NE, NE)
	75%	40.2 (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_3402_ttae3_socpt_age.sas, Output: t_3_3402_ttae3_socpt_age.rtf, Generated on: 03SEP2024 11:45,
Data Cutoff Date: 22SEP2023

Table 3.3402 Summary of Kaplan Meier Analysis of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Age Group
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Amylase increased

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	100% (100%, 100%)	100% (100%, 100%)
	Month 12	96.7% (87.5%, 99.2%)	100% (100%, 100%)
	Month 18	93.5% (79.9%, 98.0%)	100% (100%, 100%)
	Month 24	87.7% (66.2%, 95.9%)	100% (100%, 100%)
	Month 30	87.7% (66.2%, 95.9%)	100% (100%, 100%)
	Month 36	87.7% (66.2%, 95.9%)	100% (100%, 100%)
	Hazard ratio[b] (95% CI)	- (-, -)	
	p-value of 2-sided stratified log-rank test	0.1351	
	p-value from Interaction Test[c]	0.9950	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_3402_ttae3_socpt_age.sas, Output: t_3_3402_ttae3_socpt_age.rtf, Generated on: 03SEP2024 11:45,
Data Cutoff Date: 22SEP2023

Table 3.3502 Summary of Kaplan Meier Analysis of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Amylase increased

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	8 (6.0%)	0
	Censored	125 (94.0%)	136 (100%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	40.2 (23.6, NE)	NE (NE, NE)
	50%	NE (40.2, NE)	NE (NE, NE)
	75%	NE (40.2, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_3502_ttae3_socpt_reg.sas, Output: t_3_3502_ttae3_socpt_reg.rtf, Generated on: 03SEP2024 11:53,
Data Cutoff Date: 22SEP2023

Table 3.3502 Summary of Kaplan Meier Analysis of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Amylase increased

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	99.2% (94.7%, 99.9%)	100% (100%, 100%)
	Month 12	94.9% (88.1%, 97.9%)	100% (100%, 100%)
	Month 18	92.6% (83.2%, 96.8%)	100% (100%, 100%)
	Month 24	88.6% (74.1%, 95.2%)	100% (100%, 100%)
	Month 30	88.6% (74.1%, 95.2%)	100% (100%, 100%)
	Month 36	88.6% (74.1%, 95.2%)	100% (100%, 100%)
	Hazard ratio[b] (95% CI)	- (-, -)	
	p-value of 2-sided stratified log-rank test	0.0140	

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_3502_ttae3_socpt_reg.sas, Output: t_3_3502_ttae3_socpt_reg.rtf, Generated on: 03SEP2024 11:53,
Data Cutoff Date: 22SEP2023

Table 3.3502 Summary of Kaplan Meier Analysis of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Region
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Amylase increased

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	1 (1.8%)	1 (2.2%)
	Censored	55 (98.2%)	44 (97.8%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_3502_ttae3_socpt_reg.sas, Output: t_3_3502_ttae3_socpt_reg.rtf, Generated on: 03SEP2024 11:53,
Data Cutoff Date: 22SEP2023

Table 3.3602 Summary of Kaplan Meier Analysis of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Amylase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	3 (3.4%)	0
	Censored	86 (96.6%)	87 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_3602_ttae3_socpt_dstat.sas, Output: t_3_3602_ttae3_socpt_dstat.rtf, Generated on: 03SEP2024 11:56,
Data Cutoff Date: 22SEP2023

Table 3.3602 Summary of Kaplan Meier Analysis of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Amylase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	3 (8.6%)	1 (3.3%)
	Censored	32 (91.4%)	29 (96.7%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_3602_ttae3_socpt_dstat.sas, Output: t_3_3602_ttae3_socpt_dstat.rtf, Generated on: 03SEP2024 11:56,
Data Cutoff Date: 22SEP2023

Table 3.3602 Summary of Kaplan Meier Analysis of Time to Grade >=3 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Disease Status
(Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Investigations
Preferred Term: Amylase increased

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	3 (4.6%)	0
	Censored	62 (95.4%)	64 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.
Note: Analysis only includes treatment-emergent adverse events for Preferred Terms occurring in [at least 5% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].
a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).
b. Stratified Cox regression.
c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).
NE = Not Estimable.
Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].
Program: t_3_3602_ttae3_socpt_dstat.sas, Output: t_3_3602_ttae3_socpt_dstat.rtf, Generated on: 03SEP2024 11:56,
Data Cutoff Date: 22SEP2023

Table 3.3802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	14 (14.6%)	5 (6.1%)
	Censored	82 (85.4%)	77 (93.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (10.6, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3802_tt3ae_soc_age.sas, Output: t_3_3802_tt3ae_soc_age.rtf, Generated on: 20SEP2024 10:09,

Data Cutoff Date: 22SEP2023

Table 3.3802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	89.1% (80.7%, 94.0%)	94.5% (85.9%, 97.9%)
	Month 12	81.3% (69.5%, 88.9%)	94.5% (85.9%, 97.9%)
	Month 18	81.3% (69.5%, 88.9%)	91.5% (79.6%, 96.6%)
	Month 24	81.3% (69.5%, 88.9%)	91.5% (79.6%, 96.6%)
	Month 30	81.3% (69.5%, 88.9%)	91.5% (79.6%, 96.6%)
	Month 36	81.3% (69.5%, 88.9%)	91.5% (79.6%, 96.6%)
	Hazard ratio[b] (95% CI)	2.37 (0.850, 6.583)	
	p-value of 2-sided stratified log-rank test	0.0892	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3802_tt3ae_soc_age.sas, Output: t_3_3802_tt3ae_soc_age.rtf, Generated on: 20SEP2024 10:09,

Data Cutoff Date: 22SEP2023

Table 3.3802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	11 (11.8%)	1 (1.0%)
	Censored	82 (88.2%)	98 (99.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	39.9 (31.8, NE)	NE (NE, NE)
	50%	39.9 (NE, NE)	NE (NE, NE)
	75%	39.9 (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3802_tt3ae_soc_age.sas, Output: t_3_3802_tt3ae_soc_age.rtf, Generated on: 20SEP2024 10:09,

Data Cutoff Date: 22SEP2023

Table 3.3802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	93.0% (85.1%, 96.8%)	98.8% (91.5%, 99.8%)
	Month 12	88.2% (78.2%, 93.8%)	98.8% (91.5%, 99.8%)
	Month 18	88.2% (78.2%, 93.8%)	98.8% (91.5%, 99.8%)
	Month 24	88.2% (78.2%, 93.8%)	98.8% (91.5%, 99.8%)
	Month 30	88.2% (78.2%, 93.8%)	98.8% (91.5%, 99.8%)
	Month 36	80.2% (57.2%, 91.6%)	98.8% (91.5%, 99.8%)
	Hazard ratio[b] (95% CI)	>999.99 (0.000, NE)	
	p-value of 2-sided stratified log-rank test	0.0018	
	p-value from Interaction Test[c]	0.2031	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3802_tt3ae_soc_age.sas, Output: t_3_3802_tt3ae_soc_age.rtf, Generated on: 20SEP2024 10:09,

Data Cutoff Date: 22SEP2023

Table 3.3802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Number of Subjects in the Subgroup	96	82
	Status [n (%)]		
	Events observed	5 (5.2%)	3 (3.7%)
	Censored	91 (94.8%)	79 (96.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3802_tt3ae_soc_age.sas, Output: t_3_3802_tt3ae_soc_age.rtf, Generated on: 20SEP2024 10:09,

Data Cutoff Date: 22SEP2023

Table 3.3802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
<65	Survival probability (95% CI) at		
	Month 6	94.6% (87.6%, 97.7%)	97.4% (90.0%, 99.3%)
	Month 12	94.6% (87.6%, 97.7%)	97.4% (90.0%, 99.3%)
	Month 18	94.6% (87.6%, 97.7%)	93.9% (79.9%, 98.3%)
	Month 24	94.6% (87.6%, 97.7%)	93.9% (79.9%, 98.3%)
	Month 30	94.6% (87.6%, 97.7%)	93.9% (79.9%, 98.3%)
	Month 36	94.6% (87.6%, 97.7%)	93.9% (79.9%, 98.3%)
	Hazard ratio[b] (95% CI)	1.45 (0.347, 6.084)	
	p-value of 2-sided stratified log-rank test	0.6078	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3802_tt3ae_soc_age.sas, Output: t_3_3802_tt3ae_soc_age.rtf, Generated on: 20SEP2024 10:09,

Data Cutoff Date: 22SEP2023

Table 3.3802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Number of Subjects in the Subgroup	93	99
	Status [n (%)]		
	Events observed	13 (14.0%)	3 (3.0%)
	Censored	80 (86.0%)	96 (97.0%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (12.7, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3802_tt3ae_soc_age.sas, Output: t_3_3802_tt3ae_soc_age.rtf, Generated on: 20SEP2024 10:09,

Data Cutoff Date: 22SEP2023

Table 3.3802 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Age Group (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders

Age (years)	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
>=65	Survival probability (95% CI) at		
	Month 6	87.6% (78.8%, 93.0%)	97.9% (91.8%, 99.5%)
	Month 12	87.6% (78.8%, 93.0%)	95.2% (83.9%, 98.6%)
	Month 18	81.5% (68.2%, 89.6%)	95.2% (83.9%, 98.6%)
	Month 24	81.5% (68.2%, 89.6%)	95.2% (83.9%, 98.6%)
	Month 30	81.5% (68.2%, 89.6%)	95.2% (83.9%, 98.6%)
	Month 36	81.5% (68.2%, 89.6%)	95.2% (83.9%, 98.6%)
	Hazard ratio[b] (95% CI)	4.64 (1.318, 16.332)	
	p-value of 2-sided stratified log-rank test	0.0086	
	p-value from Interaction Test[c]	0.2238	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of age group (<65 vs. >=65) and treatment; in a model containing covariates: treatment group and age group (<65 vs. >=65).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3802_tt3ae_soc_age.sas, Output: t_3_3802_tt3ae_soc_age.rtf, Generated on: 20SEP2024 10:09,

Data Cutoff Date: 22SEP2023

Table 3.3902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	20 (15.0%)	5 (3.7%)
	Censored	113 (85.0%)	131 (96.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	39.9 (10.8, NE)	NE (NE, NE)
	50%	NE (39.9, NE)	NE (NE, NE)
	75%	NE (39.9, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3902_tt3ae_soc_reg.sas, Output: t_3_3902_tt3ae_soc_reg.rtf, Generated on: 20SEP2024 10:09,

Data Cutoff Date: 22SEP2023

Table 3.3902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	90.6% (84.1%, 94.6%)	95.7% (89.9%, 98.2%)
	Month 12	83.5% (74.7%, 89.5%)	95.7% (89.9%, 98.2%)
	Month 18	83.5% (74.7%, 89.5%)	95.7% (89.9%, 98.2%)
	Month 24	83.5% (74.7%, 89.5%)	95.7% (89.9%, 98.2%)
	Month 30	83.5% (74.7%, 89.5%)	95.7% (89.9%, 98.2%)
	Month 36	78.8% (64.9%, 87.7%)	95.7% (89.9%, 98.2%)
	Hazard ratio[b] (95% CI)	4.57 (1.555, 13.457)	
	p-value of 2-sided stratified log-rank test	0.0025	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3902_tt3ae_soc_reg.sas, Output: t_3_3902_tt3ae_soc_reg.rtf, Generated on: 20SEP2024 10:09,

Data Cutoff Date: 22SEP2023

Table 3.3902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	5 (8.9%)	1 (2.2%)
	Censored	51 (91.1%)	44 (97.8%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (8.9, NE)	NE (12.5, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3902_tt3ae_soc_reg.sas, Output: t_3_3902_tt3ae_soc_reg.rtf, Generated on: 20SEP2024 10:09,

Data Cutoff Date: 22SEP2023

Table 3.3902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Survival probability (95% CI) at		
	Month 6	91.8% (79.4%, 96.9%)	100% (100%, 100%)
	Month 12	88.0% (72.3%, 95.0%)	100% (100%, 100%)
	Month 18	88.0% (72.3%, 95.0%)	93.8% (63.2%, 99.1%)
	Month 24	88.0% (72.3%, 95.0%)	93.8% (63.2%, 99.1%)
	Month 30	88.0% (72.3%, 95.0%)	93.8% (63.2%, 99.1%)
	Month 36	88.0% (72.3%, 95.0%)	93.8% (63.2%, 99.1%)
	Hazard ratio[b] (95% CI)	5.34 (0.613, 46.492)	
	p-value of 2-sided stratified log-rank test	0.0913	
	p-value from Interaction Test[c]	0.7102	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3902_tt3ae_soc_reg.sas, Output: t_3_3902_tt3ae_soc_reg.rtf, Generated on: 20SEP2024 10:09,

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Table 3.3902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Number of Subjects in the Subgroup	133	136
	Status [n (%)]		
	Events observed	16 (12.0%)	6 (4.4%)
	Censored	117 (88.0%)	130 (95.6%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3902_tt3ae_soc_reg.sas, Output: t_3_3902_tt3ae_soc_reg.rtf, Generated on: 20SEP2024 10:09,
Data Cutoff Date: 22SEP2023

Table 3.3902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
North America	Survival probability (95% CI) at		
	Month 6	88.4% (81.5%, 92.8%)	96.9% (91.8%, 98.8%)
	Month 12	88.4% (81.5%, 92.8%)	95.1% (87.9%, 98.1%)
	Month 18	86.5% (78.4%, 91.8%)	92.1% (80.5%, 96.9%)
	Month 24	86.5% (78.4%, 91.8%)	92.1% (80.5%, 96.9%)
	Month 30	86.5% (78.4%, 91.8%)	92.1% (80.5%, 96.9%)
	Month 36	86.5% (78.4%, 91.8%)	92.1% (80.5%, 96.9%)
	Hazard ratio[b] (95% CI)	2.66 (1.038, 6.803)	
	p-value of 2-sided stratified log-rank test	0.0342	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3902_tt3ae_soc_reg.sas, Output: t_3_3902_tt3ae_soc_reg.rtf, Generated on: 20SEP2024 10:09,

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Table 3.3902 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Region (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders

Region	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Europe	Number of Subjects in the Subgroup	56	45
	Status [n (%)]		
	Events observed	2 (3.6%)	0
	Censored	54 (96.4%)	45 (100%)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of region (North America vs. Europe) and treatment; in a model containing covariates: treatment group and region (North America vs. Europe).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_3902_tt3ae_soc_reg.sas, Output: t_3_3902_tt3ae_soc_reg.rtf, Generated on: 20SEP2024 10:09,

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Table 3.4002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	11 (12.4%)	2 (2.3%)
	Censored	78 (87.6%)	85 (97.7%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (10.6, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_4002_tt3ae_soc_dstat.sas, Output: t_3_4002_tt3ae_soc_dstat.rtf, Generated on: 20SEP2024 10:10,

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Table 3.4002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	93.0% (85.1%, 96.8%)	97.5% (90.4%, 99.4%)
	Month 12	83.7% (70.5%, 91.3%)	97.5% (90.4%, 99.4%)
	Month 18	83.7% (70.5%, 91.3%)	97.5% (90.4%, 99.4%)
	Month 24	83.7% (70.5%, 91.3%)	97.5% (90.4%, 99.4%)
	Month 30	83.7% (70.5%, 91.3%)	97.5% (90.4%, 99.4%)
	Month 36	76.1% (54.0%, 88.5%)	97.5% (90.4%, 99.4%)
	Hazard ratio[b] (95% CI)	4.76 (1.048, 21.624)	
	p-value of 2-sided stratified log-rank test	0.0261	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

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Table 3.4002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	3 (8.6%)	1 (3.3%)
	Censored	32 (91.4%)	29 (96.7%)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

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Table 3.4002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	11 (16.9%)	3 (4.7%)
	Censored	54 (83.1%)	61 (95.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	39.9 (6.8, NE)	NE (12.5, NE)
	50%	39.9 (39.9, NE)	NE (NE, NE)
	75%	NE (39.9, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_4002_tt3ae_soc_dstat.sas, Output: t_3_4002_tt3ae_soc_dstat.rtf, Generated on: 20SEP2024 10:10,
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Table 3.4002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Infections and infestations

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	88.2% (76.7%, 94.2%)	96.5% (86.6%, 99.1%)
	Month 12	81.6% (68.1%, 89.7%)	96.5% (86.6%, 99.1%)
	Month 18	81.6% (68.1%, 89.7%)	91.7% (72.9%, 97.6%)
	Month 24	81.6% (68.1%, 89.7%)	91.7% (72.9%, 97.6%)
	Month 30	81.6% (68.1%, 89.7%)	91.7% (72.9%, 97.6%)
	Month 36	81.6% (68.1%, 89.7%)	91.7% (72.9%, 97.6%)
	Hazard ratio[b] (95% CI)	3.65 (1.015, 13.119)	
	p-value of 2-sided stratified log-rank test	0.0339	
	p-value from Interaction Test[c]	0.8861	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

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Table 3.4002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Number of Subjects in the Subgroup	89	87
	Status [n (%)]		
	Events observed	12 (13.5%)	1 (1.1%)
	Censored	77 (86.5%)	86 (98.9%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (15.1, NE)	NE (NE, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_4002_tt3ae_soc_dstat.sas, Output: t_3_4002_tt3ae_soc_dstat.rtf, Generated on: 20SEP2024 10:10,
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Table 3.4002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Recurrent	Survival probability (95% CI) at		
	Month 6	87.6% (78.7%, 92.9%)	98.9% (92.1%, 99.8%)
	Month 12	87.6% (78.7%, 92.9%)	98.9% (92.1%, 99.8%)
	Month 18	83.8% (71.0%, 91.3%)	98.9% (92.1%, 99.8%)
	Month 24	83.8% (71.0%, 91.3%)	98.9% (92.1%, 99.8%)
	Month 30	83.8% (71.0%, 91.3%)	98.9% (92.1%, 99.8%)
	Month 36	83.8% (71.0%, 91.3%)	98.9% (92.1%, 99.8%)
	Hazard ratio[b] (95% CI)	12.35 (1.605, 94.993)	
	p-value of 2-sided stratified log-rank test	0.0019	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_4002_tt3ae_soc_dstat.sas, Output: t_3_4002_tt3ae_soc_dstat.rtf, Generated on: 20SEP2024 10:10,
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Table 3.4002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Number of Subjects in the Subgroup	35	30
	Status [n (%)]		
	Events observed	3 (8.6%)	2 (6.7%)
	Censored	32 (91.4%)	28 (93.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (12.7, NE)	NE (10.1, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_4002_tt3ae_soc_dstat.sas, Output: t_3_4002_tt3ae_soc_dstat.rtf, Generated on: 20SEP2024 10:10,
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Table 3.4002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage III	Survival probability (95% CI) at		
	Month 6	94.0% (78.1%, 98.5%)	96.2% (75.7%, 99.4%)
	Month 12	94.0% (78.1%, 98.5%)	90.5% (66.2%, 97.6%)
	Month 18	86.2% (58.5%, 96.0%)	90.5% (66.2%, 97.6%)
	Month 24	86.2% (58.5%, 96.0%)	90.5% (66.2%, 97.6%)
	Month 30	86.2% (58.5%, 96.0%)	90.5% (66.2%, 97.6%)
	Month 36	86.2% (58.5%, 96.0%)	90.5% (66.2%, 97.6%)
	Hazard ratio[b] (95% CI)	1.25 (0.208, 7.480)	
	p-value of 2-sided stratified log-rank test	0.8084	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_4002_tt3ae_soc_dstat.sas, Output: t_3_4002_tt3ae_soc_dstat.rtf, Generated on: 20SEP2024 10:10,
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Table 3.4002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Number of Subjects in the Subgroup	65	64
	Status [n (%)]		
	Events observed	3 (4.6%)	3 (4.7%)
	Censored	62 (95.4%)	61 (95.3%)
	Estimates for TEAE (months) Quartile (95% CI)[a]		
	25%	NE (NE, NE)	NE (16.6, NE)
	50%	NE (NE, NE)	NE (NE, NE)
	75%	NE (NE, NE)	NE (NE, NE)

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_4002_tt3ae_soc_dstat.sas, Output: t_3_4002_tt3ae_soc_dstat.rtf, Generated on: 20SEP2024 10:10,
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Table 3.4002 Summary of Kaplan Meier Analysis of Time to Treatment-Emergent Adverse Events by System Organ Class by Disease Status (Safety Analysis Set): MMRp/MSS Subjects

System Organ Class: Vascular disorders

Disease Status	Variable	Dostarlimab + Carboplatin/Paclitaxel (N=189)	Placebo + Carboplatin/Paclitaxel (N=181)
Primary Stage IV	Survival probability (95% CI) at		
	Month 6	95.0% (85.2%, 98.3%)	96.7% (87.4%, 99.2%)
	Month 12	95.0% (85.2%, 98.3%)	96.7% (87.4%, 99.2%)
	Month 18	95.0% (85.2%, 98.3%)	91.0% (69.4%, 97.6%)
	Month 24	95.0% (85.2%, 98.3%)	91.0% (69.4%, 97.6%)
	Month 30	95.0% (85.2%, 98.3%)	91.0% (69.4%, 97.6%)
	Month 36	95.0% (85.2%, 98.3%)	91.0% (69.4%, 97.6%)
	Hazard ratio[b] (95% CI)	1.00 (0.202, 4.948)	
	p-value of 2-sided stratified log-rank test	0.9986	
	p-value from Interaction Test[c]	0.1450	

Note: TEAE: Treatment-Emergent Adverse Event.

Note: Analysis only includes treatment-emergent adverse events for System Organ Classes occurring in [at least 10% of patients in any treatment arm] OR in [at least 10 patients AND at least 1% of patients in any treatment arm within the population].

a. 95% Confidence intervals generated using the method of Brookmeyer and Crowley (1982).

b. Stratified Cox regression.

c. Based on a Stratified Cox Regression model for the interaction of disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV) and treatment; in a model containing covariates: treatment group and disease status (Recurrent vs. Primary Stage III vs. Primary Stage IV).

NE = Not Estimable.

Note: In case of 0 events in one treatment arm, H.R is produced using cox proportional hazard model with Firth's correction(Firth 1993) and the corresponding 95% confidence for H.R will be constructed using the profile likelihood method [Heinze and Schemper 2001].

Program: t_3_4002_tt3ae_soc_dstat.sas, Output: t_3_4002_tt3ae_soc_dstat.rtf, Generated on: 20SEP2024 10:10,
Data Cutoff Date: 22SEP2023